

***United States Court of Appeals
for the Second Circuit***



APPENDIX

77-7097

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

-----X
THE MEDICAL SOCIETY OF THE STATE OF NEW :
YORK, a New York not-for-profit corpor- :
ation, MORTON M. KOFF, M.D., MILTON :
ROSENBERG, M.D., and JANE DOE, :

Plaintiffs-Appellees. :

-against- :

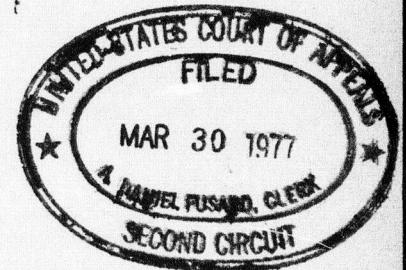
PHILIP TOIA, as Commissioner of the :
Department of Social Services, and :
ROBERT P. WHALEN, M.D., as Commissioner :
of Health of the State of New York, :

Defendants-Appellants. :
-----X

ON APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE EASTERN
DISTRICT OF NEW YORK

APPENDIX

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FOR THE SECOND CIRCUIT

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THE MEDICAL SOCIETY OF THE STATE OF NEW :
YORK, a New York not-for-profit corpor- :
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of Health of the State of New York, :

Defendants-Appellants. :
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ON APPEAL FROM THE UNITED STATES
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PLAINTIFFS

DEFENDANTS

x | MEDICAL SOCIETY OF NYS et al |

| TOIA, PHILIP et ano |

THE MEDICAL SOCIETY OF THE STATE
OF NEW YORK, a New York not-for-
profit corporation, MORTON M. KOFF,
M.D., and JANE DOE

PHILIP TOIA, as Commissioner of the
Department of Social Services
of the State of New York and
ROBERT P. WHALEN, M.D. as
Commissioner of the Department of
Health of the State of New York

CAUSE

42 U.S.C. § 1396
SEEKS DECLARATORY JUDGMENT ON GROUNDS THAT Chap. 76 of NYS LAW, 1976
VIOLATE CONSTITUTION

ATTORNEYS

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			JS-6	

PROCEEDINGS

8-5-76	Complaint filed. Summons issued.	(1)
8-5-76	Clerk's order to allow personal service for summons & complaint filed.	(2)
8-5-76	Affidavit of C. Sifton filed.	(3)
8-9-76	Order to appoint person to serve process filed.	(4)
8-11-76	Summons ret and filed/affidavit of service annexed.	(5)
XXXXXX	XX	
8-20-76	Clerk's order to appoint person to serve process filed.	(6)
- -	Stop summons issued.	(7)
8-20-76	Amended complaint filed.	(8)
8-23-76	Affidavit in opposition to preliminary injunction filed.	(9)
8-23-76	Defts' memorandum in opposition filed.	(10)
8-23-76	Affidavit of James D. Wharton filed.	(11)(12)
8-24-76	Pltff's reply memo of law with appendices for preliminary injunction filed.	
8-25-76	BY PRATT, J. - Order to show cause ret 8-26-76 at 9:00 AM why an order should not be entered enjoining defts pending disposition of act from enforcing or implementing said Secs. 3&4 of Chapter 76 of the laws of 1976 etc. filed without proof of service.	(12)
8-25-76	Memorandum of law in support of application for preliminary injunction etc. filed.	(13)
8-25-76	Affidavit in opposition to a preliminary injunction filed.	(14)
8-31-76	Supp memo of law for preliminary injunction filed.	(15)
8-31-76	Affidavit of F. Cicero in opposition to preliminary injunction filed.	(16)
8-31-76	Affidavit of J. Diehl with memo of law in opposition to motion preliminary injunction filed.	(17)(18)
9-16-76	ANSWER filed.	(19)
1-18-77	BY PRATT, J.- memorandum and order granting the plaintiffs' motion for a preliminary injunction insofar as it challenges restrictions imposed by Section 3 of Chapter 76 on reimbursible surgical costs, and denying the motion insofar as it challenges restrictions imposed by Sections 3 and 4 of Chapter 76 on reimbursable costs on non-surgical hospital care etc. filed. Settle order on notice.	(20)
1-20-77	BY PRATT, J.- order amending memo and order of 1-18-77 filed. Copies mailed to parties.	(21)
1-25-77	By PRATT, J.- Order granting pltff's motion for preliminary injunction to the extent that the defts are restrained from implementing that section of the Social Services Law of NYS, pending the determination of this action and that pltff's motion for a preliminary injunction in all other respects is denied filed. Copise mailed.	(22)
2-11-77	Notice of motion ret. 2-14-77 at 2:00 PM for a stay pending appeal of this Court's order of 1-25-77 etc. filed with memo of law.	(23/24)
-16-77	By Pratt, J.- order dtd 2-15-77 denying sua sponte defts' motion ret 2-24-77 for a stay pending appeal of the Court's order of 1-25-77, filed. Copies sent to parties.	(25)
2-18-77	Notice of appeal filed by NYS.	(26)
3-7-77	Civil appeal scheduling order filed.	(27)

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 [Signature]
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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
MEDICAL SOCIETY, et al.,

Plaintiffs,

- against -

TOIA, et al.,

Defendants.
-----X

File
NOTICE OF APPEAL

76 CIV 1443
G.C.P.

S I R S :

PLEASE TAKE NOTICE that the defendants appeal from this Court's judgment and order of January 25, 1977 to the United States Court of Appeals for the Second Circuit in so far as the aforesaid judgment granted plaintiffs relief. Defendants appeal from each and every part of that portion of the aforesaid judgment which granted plaintiffs relief.

Dated: New York, New York
February 15, 1977

Yours, etc.,

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JAN 27 1977

DEPARTMENT OF LAW
NEW YORK CITY OFFICE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- - - - - x
THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., JANE DOE,
and RAYMOND ORTEGA, a seventeen year
old infant, by his next friend and
parent, RICARDA ORTEGA,

DOCKET NO. 76 C 1443

ORDER

Plaintiffs,

- against -

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P.
WHALEN, M.D., as Commissioner of the
Department of health of the State of
New York,

Defendants.

- - - - - x

On the basis of the findings of fact and con-
clusions of law set forth in the court's memorandum and order
of January 18, 1977, as amended by its order of January 20,
1977, it is

ORDERED, that plaintiffs' motion for a pre-
liminary injunction is granted to the extent that defendants,
their agents, servants, and employees and all persons in
active concert and participation with them be and each of
them hereby is restrained and enjoined, pending the determina-
tion of this cause, from implementing or enforcing Subdivision

five (a), (b), (c) and (e) of Section 365-a of the Social Services Law of the State of New York; and it is further

ORDERED, that plaintiffs' motion for a preliminary injunction be, and it hereby is in all other respects denied.

The court finds that plaintiffs need not supply an undertaking. (See State of Alabama ex rel. Baxley v. Corps of Engineers of the United States Army, 411 F Supp 1261, 1275-76 (ND Ala 1976), and cases cited therein.)

SO ORDERED.

Dated: Westbury, New York
January 25, 1977

5/
GEORGE C. PRATT
U. S. DISTRICT JUDGE

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y.

★ JAN 18 1977 ★

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

TIME A.M. _____
P.M. _____

----- x
THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE
DOE,

DOCKET NO. 76 C 1443

Plaintiffs,

- against -

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P.
WHALEN, M.D., as Commissioner of the
Department of Health of the State of
New York,

MEMORANDUM AND ORDER

Defendants.

----- x
PRATT, J:

On March 30, 1976, Chapter 76 of the Laws of New
York, 1976 (Chapter 76) was signed into law, amending New York
Social Services Law (NYSSL) §365-a. Plaintiffs seek to enjoin
the enforcement of Sections 3 and 4 of Chapter 76 and the
regulations issued thereunder on the ground that they limit
medical costs reimbursable under New York's federally subsi-
dized medical assistance (Medicaid) program in violation of
the Federal Constitution, the Constitution of New York State,
the Social Security Act, and pertinent federal regulations.

Currently before the court is plaintiffs' motion for a preliminary injunction. On the basis of the factual findings^{1./} and legal conclusions set forth below, the motion is granted insofar as it challenges restrictions imposed by Section 3 of Chapter 76 on reimbursable surgical costs, and denied insofar as it challenges restrictions imposed by Sections 3 and 4 of Chapter 76 on reimbursable costs of non-surgical hospital care.

I. THE PARTIES

The amended complaint names as plaintiffs the Medical Society of the State of New York (the Medical Society), Morton M. Koff, M.D., Milton Rosenberg, M.D., Jane Doe, and Raymond Ortega, a seventeen year-old suing by his parent Richard Ortega.

The Medical Society is a New York not-for-profit corporation purportedly organized to provide administrative assistance to its 28,000 physician members and to enhance "the delivery of medical care of high quality to all people in the most economical manner".

Drs. Rosenberg and Koff are physicians licensed to practice in New York and members of the Medical Society. Both

treat a substantial number of patients covered by Medicaid. Rosenberg specializes in obstetrics and gynecology; Koff in family medicine. Rosenberg performs surgery; Koff does not.

Jane Doe is a resident of New York who is receiving assistance under the Aid for Families with Dependent Children (AFDC) provisions of the Social Security Act, 42 USC §601 et seq., and therefore qualifies for assistance under New York's Medicaid program. NYSSL §366(1)(a)(1); 42 USC §1396a(a)(10)(A). She suffers from abnormally voluminous and frequent menstrual bleeding. Her physician, a Dr. Seinfeld, has recommended that she undergo a dilatation and curettage, a surgical procedure normally performed on women in her condition. Although previously this procedure was covered by New York's Medicaid program, Dr. Seinfeld has not performed it on her because of her inability to pay for it and his belief that its coverage by Medicaid was terminated by Chapter 76.

Raymond Ortega is a seventeen year-old resident of New York. He also is receiving assistance under the AFDC program and accordingly qualifies for assistance under New York's Medicaid program. At the age of seven, he suffered extensive second and third-degree burns on his face, neck, and chest. As a result, he has received multiple skin grafts.

However, he still suffers from a severe burn scar of the right side of the face which causes an ectropion of the right lower eyelid and a significant contracture at the angle of the mouth. His scars concededly "cause him severe social embarrassment and emotional trauma plus further physical debilitation". Affidavit of Hugh O'Neil, Deputy Commissioner of New York State's Department of Social Services, filed August 3, 1976, at 2-3. Consequently, Ortega's physician, Dr. Kisner, has recommended corrective surgery. It has been deferred, however, on the doctor's belief that, because of the enactment of Chapter 76, it is no longer reimbursable under New York's Medicaid program.

The amended complaint names two defendants: Philip Toia, Commissioner of New York's Department of Social Services, and Robert P. Whalen, M.D., Commissioner of the state's Department of Health.

II. THE TWENTY DAYS PER ILLNESS LIMITATION ON REIMBURSABLE HOSPITAL CARE

Plaintiffs seek to enjoin preliminarily the enforcement of Sections 3 and 4 of Chapter 76. Section 4 amends NYSSL §365-a(2)(b) to provide in part that

in-patient care, services and supplies in a general hospital shall not exceed such standards as the commissioner of health shall promulgate but in no case greater than twenty days per spell of illness during which all or any part of the cost of such care, services and supplies are claimed as an item of medical assistance, unless it shall have been determined in accordance with procedures and criteria established by such commissioner that a further identifiable period of in-patient general hospital care is required for particular patients to preserve life or to prevent substantial risks of continuing disability.

To the extent that the instant motion seeks to enjoin the enforcement of this provision, it must be denied, for plaintiffs have failed to make the necessary clear showing of possible irreparable injury resulting from the provision's continued enforcement. See, e.g., Diversified Mortgage Investors v. United States Life Title Insurance Co. of New York, No. 75-7428, slip op. at 4544 (CA2 June 30, 1976). The record is devoid of evidence relevant to the potential effect of the restrictions imposed upon reimbursable hospital care by Section 4 of Chapter 76.

III. THE PRESUMPTIVE ONE-DAY LIMITATION ON REIMBURSABLE PRE-OPERATIVE HOSPITAL CARE

Section 3 of Chapter 76 adds a fifth subdivision

to NYSSL §365-a. The new subdivision (5) provides:

(a) Medical assistance shall include surgical benefits for emergency or urgent surgery for the alleviation of severe pain, for immediate diagnosis or treatment of conditions which threaten disability or death if not promptly diagnosed or treated.

(b) Medical assistance shall include surgical benefits for certain surgical procedures which meet standards for surgical intervention, as established by the state commissioner of health on the basis of medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with such surgical intervention.

(c) Medical assistance shall include surgical benefits for other deferrable surgical procedures specified by the state commissioner of health, based on the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function, or cause severe pain; provided, however, such procedures shall be included in the case of in-patient surgery, except surgery authorized pursuant to paragraph (a) of this subdivision, only when a second written opinion is obtained from a physician, or as otherwise prescribed, in accordance with regulations established by the state commissioner of health, that such surgery should not be deferred.

(d) Medical assistance shall include a maximum of one patient day of pre-operative hospital care for surgery authorized by paragraphs (b) or (c) of this subdivision; provided, however, that with respect to specific surgical procedures which the state commissioner of health has identified as requiring more than one patient day of pre-operative care, medical assistance shall include such longer maximum period of pre-operative care as such commissioner has identified as neces-

sary.

(e) Medical assistance shall not include any in-patient surgical procedures or any care, services or supplies related to such surgery other than those authorized by this subdivision.

To the extent that plaintiffs seek to enjoin preliminarily the enforcement of paragraph (d) of this new subdivision (imposing a presumptive one-day limitation on reimbursable pre-operative hospital care), their motion must be denied. Here, too, plaintiffs have failed to make the requisite clear showing of possible irreparable injury.

The only relevant evidence is found in two portions of the deposition of Dr. Edgar Altchek. There, at page 17, the doctor was asked whether, if Ortega obtained the recommended operation, it was "possible that pre-operative testing would limit [his hospital] stay to one day prior to surgery", the maximum period of pre-operative inpatient care presumptively reimbursable under paragraph (d). The doctor answered, "No. The patient would have to be admitted the day before surgery in any case, no matter what pre-operative tests were done before he was admitted." While this response possibly reflects the doctor's misunderstanding of the question posed, it does not indicate that more than one day of pre-

operative inpatient care would have been necessary in Ortega's case. See also discussion of 10 New York Code of Rules and Regulations (NYCRR) §85.4(a), infra.

The other portion of Altchek's deposition that is arguably relevant to the potential impact of enforcement of NYSSL §365-a(5)(d) pendente lite is the following:

Q Turning to those provisions of the State which state medical assistance is limited to a maximum of one day of pre-operative care, except with respect to specific surgical procedures, which the State Commissioner of Health has identified as requiring more than one day of pre-operative care, would you state whether in your opinion the duration of appropriate pre-operative care can be determined solely on the basis of the type of operation for which the patient is scheduled?

A Not at all.

Q What other factors must be considered in every case?

A The chief factor is the patient himself. We're operating upon a patient and we don't tailor the patient to fit the operation. We suit the operation to the patient and the patient himself may have underlying medical conditions that require that he be in the hospital for more than one day. For example, it may be necessary to perform certain tests and to determine his fitness for surgery.

It may be necessary to prepare him medically for surgery. You cannot predict, you cannot legislate the length of a stay of any particular patient that may require surgery.

Deposition of Dr. Edgar Altchek,
August 27, 1976, at 14.

A

To be properly evaluated, this testimony must be viewed in light of the regulation, 10 NYCRR §85.4, promulgated by the defendant Commissioner of Health to implement paragraph (d) of NYSSL §365-a(5). The regulation provides in pertinent part:

(a) To be a covered benefit under medical assistance for the needy, provided in section 365-a(5)(d) of the Social Services Law, any pre-surgical hospital stay of more than one day for surgical benefits covered by sections 365-a(5)(b) and 365-a(5)(c) shall require a determination of coverability prior to admission by a person designated by the commissioner of health. * * * A determination of coverability shall be based upon existence of conditions which require inpatient preparation of more than one day to improve operative risk status such as:

(1) correction of significant fluid or electrolyte imbalance.

(2) transfusion to correct significant anemia.

(3) stabilization of congestive heart failure.

(4) improvement of pulmonary function or drainage.

(5) hyperalimentation to correct significant malnutrition.

(6) gastro-intestinal preparation before gastrointestinal surgery.

(7) stabilization of significant endocrine disorder.

(8) hematologic and immunologic preparation for organ transplant.

(9) management of infection.

(10) essential preliminary studies and procedures performable only on an inpatient basis.

In the testimony quoted previously from Dr. Altchek's deposition, he indicated that the duration of appropriate pre-operative care cannot be determined solely on the basis of the type of operation to be performed. But the regulation implementing paragraph (d) of NYSSL §365-a(5) does not attempt to determine the duration of reimbursable pre-operative care solely on the basis of this criterion. And while the language of paragraph (d) may be difficult to reconcile with that of the regulation, no evidence elicited thus far indicates that the regulation is not being applied as it reads.

Altchek also testified that the duration of appropriate pre-operative care varies according to a patient's particular needs. But §85.4(a) seeks to allow for the reimbursement of additional pre-operative care on precisely that basis.

In short, neither Altchek's testimony nor any other evidence currently before the court indicates that continued enforcement of paragraph (d) of NYSSL §365-a(5) might cause an eligible person to be denied full Medicaid coverage for appropriate pre-operative inpatient care. Thus, plaintiffs have failed to make the requisite showing that some irreparable

injury might be averted by a preliminary injunction against enforcement of paragraph (d).

IV. THE LIMITATION OF REIMBURSABLE SURGICAL PROCEDURES

Remaining to be considered are paragraphs (a), (b), (c) and (e) of NYSSL §365-a(5), added by Section 3 of Chapter 76 of the Laws of 1976. Plaintiffs contend that these provisions impermissibly limit the scope of surgical procedures reimbursable under New York's Medicaid program. Plaintiffs base this contention upon federal and state constitutional grounds, as well as upon the "statutory" argument that the contested provisions are void under the Constitution's supremacy clause because they violate federal statutory and regulatory law. But determination of the instant motion necessitates full consideration of only the "statutory" argument. Moreover, as will become apparent, in addressing this argument it is not necessary to focus upon any plaintiffs other than the Medical Society.

A. The Medical Society Has Article III Standing.

The Society's interest in invalidating the limitations imposed upon reimbursable surgical procedures by §365-a(5) is sufficient to satisfy Article III's jurisdictional require-

ment of a "case or controversy".

[A]n association may have standing solely as the representative of its members. E.g., National Motor Freight Traffic Assn. v. United States, 372 U.S. 246, 83 S. Ct. 688, 9 L.Ed.2d 709 (1963). The possibility of such representational standing, however, does not eliminate or attenuate the constitutional requirement of a case or controversy. See Sierra Club v. Morton, 405 U.S. 727, 92 S.Ct. 1361, 31 L.Ed.2d 636 (1972). The association must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit. Id., at 734-741, 92 S.Ct., at 1365-1369. So long as this can be established, and so long as the nature of the claim and of the relief sought does not make the individual participation of each injured party indispensable to proper resolution of the cause, the association may be an appropriate representative of its members, entitled to invoke the court's jurisdiction. Warth v. Seldin, 422 US 490, 511 (1975).

Here, the Society is suing on behalf of 28,000 member physicians. That many of these doctors are suffering immediate injury as a result of §365-a(5) is clearly indicated by allegations in the complaint and established by affidavits which specifically assert that the contested provision precludes the compensation of these doctors under New York's Medicaid program for surgical procedures for which they were

regularly reimbursed prior to the provision's enactment. Whether the doctors are suffering immediate harm because of the provision is not left to speculation. See City of Hartford v. Towns of Glastonbury, West Hartford, and East Hartford, No. 76-6049 (CA2, Dec. 23, 1976); compare Warth v. Seldin, supra at 507, 516. Consequently, since New York State has a substantial financial interest in opposing the Society, "[t]he relationship between the parties is classically adverse, and there clearly exists between them a case or controversy in the constitutional sense." Singleton v. Wulff, 96 S Ct 2868, 2873 (1976).

Moreover, here "the nature of the claim and of the relief sought does not make the individual participation of each injured party indispensable to proper resolution of the cause". Since the complaint makes no claim for damages, no individualized proof is necessary to establish the relief sought by the Society on behalf of its members. Compare Warth v. Seldin, supra at 515-16. The Society asks only for prospective declaratory and injunctive relief; thus, "it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured." Id. at 515.

A

B. The Medical Society May Assert the Rights of its Members' Patients.

The Medical Society seeks to assert its members' constitutional rights to practice medicine, but it is not now necessary to determine whether such rights exist, for under the circumstances here the Society may assert the rights of its members' patients, and those rights are sufficient to dispose of this motion. Singleton v. Wulff, 96 SCt 2868 (1976).

There, two physicians were held to have standing to assert their patients' rights against Missouri's Medicaid program's restriction of its coverage of abortions to those which were medically indicated. Writing for a plurality of four, Justice Blackmun found that only two justifications existed for the general rule that courts should not resolve a controversy on the basis of the rights of third parties. The first was that courts should not adjudicate the rights of third parties "unnecessarily"; the second that "third parties themselves usually will be the best proponents of their own rights". Id. 2873-74.

Here, as in Wulff, neither of these justifications applies. To begin with, the adjudication of rights of the Medical Society's members' patients is not "unnecessary".

Since the patients' enjoyment of any right which might be infringed by the provisions contested here is "inextricably bound up with the activity the [Society's members wish] to pursue, the court at least can be sure that its construction of the right is not unnecessary in the sense that the right's enjoyment will be unaffected by the outcome of the suit".

Id. at 2874. And this is certainly not a case where third parties do not wish their rights asserted for them. Furthermore, determination of the validity of the provisions contested here does not require adjudication of any possible conflict between them and the patients' rights under the Constitution. See id. at 2874, citing Ashwander v. TVA, 297 US 288, 345-48 (1936) (Brandeis, J., concurring).

The second justification articulated by the plurality in Wulff for the general rule against the assertion of rights of third parties does not apply here either, since the Society can be expected to be a better advocate of the rights of its members' patients than the patients themselves. Individual patients who are eligible for Medicaid are not apt to have sufficient financial resources to bring a suit by themselves. Nor is there likely to be sufficient financial incentive to prompt them to do so. And the possibility of

their forming an association to litigate their claims jointly is unlikely. In short, there are serious obstacles to the individual patient's assertion of his right to the Medicaid coverage at issue here.

The Medical Society, on the other hand, is confronted with none of these obstacles; it lacks neither adequate resources nor adequate incentive. No significant conflict exists between the objectives of the Society and those of the patients whose rights it asserts, and because of the intimacy of the doctor-patient relationship, the Society is highly sensitive to the patient viewpoint.

In sum, both justifications identified by the Court in Wulff for not allowing the assertion of third-party rights are absent here. Consequently, under the analysis of the four-justice plurality, before denying the relief sought by the Society, this court should consider the rights of the patients of the association's members..

The opinion of a fifth justice in Wulff also supports this conclusion. In a concurring opinion, Justice Stevens expressed uncertainty about the adequacy of the plurality's analysis of this particular issue; however, he

agreed that the issue had been correctly decided because of the presence of two additional facts: "(1) the plaintiffs-physicians [had] a financial stake in the outcome of the litigation, and (2) they claim[ed] that the statute impair[ed] their own constitutional rights". Id. at 2877. Since the same facts are present here, the Society's standing to invoke its members' patients' rights is supported by the reasoning of a majority of the Court in Wulff.

C. Subject Matter Jurisdiction.

The court has subject matter jurisdiction on the basis of 28 USC §1343, and principles of pendent jurisdiction. 2./

Section 1343(3) provides in pertinent part that "district court shall have original jurisdiction of any civil action authorized by law to be commenced by any person * * * [t]o redress the deprivation, under color of any State * * * statute * * *, of any right * * * secured by the Constitution of the United States * * *." Invoking the authority of 42 USC §1983, the instant complaint seeks relief from NYSSL §365-a(5) on the ground, inter alia, that it violates the Constitution by conditioning reimbursement for certain "deferrable" surgery on the obtaining of a "second written opinion * * * that such surgery should not be deferred".

NYSSL §365-a(5)(c). Since a second written opinion necessitate an additional physical examination of the patient by someone other than his doctor, see 10 NYCRR §85.3(d), it is argued that the "second opinion" requirement violates the constitutional right to privacy of affected patients, especially where the surgery sought is of a highly personal nature.

This argument finds support in Roe v. Ingraham, 403 F Supp 931 (SDNY 1975), probable jurisdiction noted in 96 SCt 1100 (1976). There a three-judge court held that "so much of the New York Health Law as require[d] reporting to state authorities * * * the names and addresses of patients [receiving certain narcotic] drugs as medication prescribed by duly licensed physicians [was] an unconstitutional interference with [the patients'] rights of privacy guaranteed under the Fourteenth Amendment." Id. at 938. After conceding that a compelling state interest would warrant limitation of these rights, the court concluded that the regulatory scheme challenged there was unconstitutional because of its "needlessly broad sweep".

Defendants contend that the privacy claim asserted here is "insubstantial" and therefore cannot support jurisdiction under 28 USC §1343(3). But, in light of Roe v.

Ingraham and the very minimal standards of merit required before a district court may assume jurisdiction of a claim under §1343(3), see Hagans v. Lavine, 415 US 528, 536-38 (1974), this court cannot agree. Whatever might be the ultimate resolution of the privacy claim on the merits, it is not "obviously frivolous" or "so attenuated as to be absolutely devoid of merit", id. at 537.

D. The Court Has Pendent Jurisdiction Over the "Statutory" Claim and May Decide It Without the Convening of a Three-Judge Panel.

Since the court has jurisdiction over the constitutional claim to privacy under §1343(3), it has pendent jurisdiction over the complaint's "statutory" attack on the same section of the act. See United Mine Workers v. Gibbs, 383 US 751 (1966); Rosado v. Wyman, 397 US 397, 402-04 (1970); Hagans v. Lavine, 415 US 528, 549-50 (1974); Schneider v. Whaley, 541 F2d 916, 918-19 (CA2 1976). The "statutory" issue must be decided first in order to avoid an unnecessary adjudication of any of the complaint's constitutional claims. Hagans v. Lavine, supra at 549-50, Schneider v. Whaley, supra at 919. And since the "statutory" claim constitutes a sufficient basis for preliminarily enjoining the enforcement of paragraphs (a), (b), (c) and (e) of NYSSL §365-a(5), the convening of a three-

judge panel on the constitutional questions is not now necessary.^{3./} Hagans v. Lavine, supra at 543-44; Friedman v. Berger, No. 76-7187 (CA2 Dec. 8, 1976).

E. Do the State Statute's Limitations on Reimbursable Surgery Violate the Social Security Act?

The Medical Society contends that paragraphs (a), (b), (c) and (e) of NYSSL §365-a(5) violate Title XIX of the Social Security Act, 42 USC §1396 et seq., and regulations promulgated thereunder, 45 CFR §249.10 et seq. The Society bases this contention on three independent rationales:

(1) that paragraphs (a), (b), (c) and (e) preclude reimbursement for certain "inpatient hospital services" and "physicians' services" whose reimbursement is required by 42 USC §1396a(a)(13);

(2) that these provisions "arbitrarily deny * * * services * * * solely [on the basis of] diagnosis, type of illness or condition" in violation of 45 CFR §249.10 (a)(5)(i); and

(3) that they violate the requirement of 42 USC §1396a(19) that a state's Medicaid plan must assure that "eligibility for care and services under the plan will be determined * * * in a manner consistent with simplicity of

administration and the best interests of the recipients".

On the basis of the evidence now before it, the court concludes that the first of these arguments is valid and that consideration of the latter two is therefore not now necessary.

Under 42 USC §1396d(a)(5), reimbursable medical care is defined to include, inter alia, "physicians' services furnished by a physician". Defendants concede that "the Social Security Act requires that these services be furnished to all eligible individuals". Defendants' Memorandum filed Aug. 23, 1976, at 21. See 42 USC §§1396a(a)(13)(B) and (C).^{4./} At issue here is whether NYSSL §365-a(5) denies reimbursement for certain of these mandated services.

The enactment of this provision constituted an attempt to limit NYSSL §365-a(2) which had extended Medicaid coverage to

part or all of the cost of care, services and supplies which are necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with his capacity for normal activity, or threaten some significant handicap * * *.

Paragraph (e) of subdivision (5) of §365-a limits the state's

Medicaid program's coverage of inpatient surgical procedures and related services to those authorized in paragraphs (a), (b) and (c) of the same subdivision. Paragraph (a) provides coverage only where "emergency or urgent surgery" is performed "for the alleviation of severe pain [or] for immediate diagnosis or treatment of conditions which threaten disability or death if not promptly diagnosed or treated". See 10 NYCRR §85.1. As implemented by state regulation, see 10 NYCRR §85.2(a), paragraph (b) provides coverage for the following procedures only: (1) cataract surgery to restore vision, (2) certain eye muscle surgery, (3) myringotomy, (4) tubal ligation or vasectomy to interdict conception, and (5) termination of pregnancy. And finally, subparagraph (c) provides coverage for "other deferrable surgical procedures specified by the state commissioner of health, based on the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function, or cause severe pain".

The dilatation and curettage sought by Jane Doe is one example of a medical service whose coverage the Society claims to be precluded by the contested state statute but mandated by federal law. On the basis of the deposition of Doe's physician, Dr. Seinfeld, the court finds (1) that Doe

was suffering abnormally voluminous and frequent (bi-weekly) menstrual bleeding, (2) that dilatation and curettage constituted the usual therapeutic treatment of her condition, (3) that in her case the operation was not needed to diagnose her condition, (4) that the condition caused her considerable inconvenience and discomfort, (5) that it nevertheless caused her no significant pain, and (6) that it was not likely to be significantly worsened by her inability to obtain a dilatation and curettage for a six-month period.

Given these circumstances, the operation sought by Doe would not be reimbursable under any reasonable construction of paragraphs (a), (b) or (c) of §365-a(5). In affidavits submitted in opposition to the instant motion, defendants have suggested that the procedure was covered under paragraph (a) as necessary to "immediate diagnosis * * * of conditions which threaten disability or death if not promptly diagnosed". But, as noted above, here the operation was not needed to diagnose Doe's condition, much less one threatening disability or death if not promptly diagnosed.

Thus, NYSSL §365-a(5) denies reimbursement for the operation prescribed for Doe. Does the Social Security Act require that it be covered by New York's Medicaid program?

The answer to this question depends upon whether the dilatation and curettage sought by Doe constitutes a "physicians' service" under 42 USC §1396d(a)(5). If it does, it is required to be reimbursed under the state program. 42 USC §1396a(a)(13)(B).

The term "physicians' services" is defined by federal regulation as "those services provided, within the scope of practice of his profession as defined by State law, by or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy". 45 CFR §249.10(b)(5). Some recent cases have indicated that "physicians' services" should be construed to mean only "medically necessary" physicians' services. Klein v. Nassau County Medical Center, 347 F Supp 496, 499 (EDNY 1972) (three-judge court), vacated and remanded on other grounds, 410 US 179 (1973); Doe v. Beal, 523 F2d 611, 618-20 (CA3 1975) (en banc); Coe v. Hooker, 406 F Supp 1072, 1081 (D NH 1976); cf. Roe v. Norton, 522 F2d 928 (CA2 1975). However, none of these cases defines the qualifying term "medically necessary" with any specificity, nor applies it in a manner that is very instructive here.

Defendants propose two definitions of the term. They argue first that "medically necessary" should be construed

to mean medically indicated, i.e., "not needless". This interpretation is reasonable and finds substantial support in a number of federal statutory and regulatory Medicaid provisions. E.g., 42 USC §§1396a(a)(4)(A) and (33)(A); 45 CFR §249.10(a)(5)(i). Here, however, the operation sought by Doe has been shown to be medically indicated. It is the usual therapeutic treatment for a condition which causes Doe both inconvenience and discomfort.

Defendants propose a second interpretation of the "medically necessary" limitation on the statutory term, "physicians' services". Specifically, they propose to define a "medically necessary surgical procedure" as one whose performance is necessary to prevent a possible "curtailment of the patient's ability to function adequately in our society". However, at least to the extent that it does not apply to operations which are both medically indicated and ordinarily performed (such as that sought by Doe), this definition would contravene the straightforward language of the federal statute -- "physicians' services furnished by a physician".

This conclusion derives strong support from HEW's construction of the statutory language to mean "services provided [by a licensed physician] within the scope of practice

of his profession as defined by State law". 45 CFR §249.10(b)(5). Friedman v. Berger, No. 76-7187, slip op. at 848 (CA2 Dec. 8, 1976), and cases cited therein. See also Letter of Bernice L. Bernstein, Regional Director for Region II, Department of Health, Education, and Welfare, to the Governor of the State of New York, dated March 29, 1976, at 2 (excerpted infra).

Accordingly, the court is constrained to conclude that NYSSL §365-a(5) violates the Social Security Act by denying Medicaid coverage for dilatation and curetage procedures to eligible individuals with medical conditions like that of plaintiff Doe. 42 USC §§1396a(a)(13) and d(a)(5).^{5./}

The dilatation and curettage prescribed for Doe is but one example of a surgical procedure for which Medicaid coverage is mandated by the Social Security Act, yet denied by NYSSL §365-a(5). There are others.^{6./} The state provision denies reimbursement for certain operations which, though medically indicated, are deferrable, i.e., where "deferral of [the operation] for six months or more may jeopardize life or essential function, or cause severe pain". However, under the Social Security Act, if an eligible person seeks an operation which is medically indicated and ordinarily performed on other

persons in comparable medical circumstances, then that person is entitled to Medicaid coverage. The Act does not authorize the state to condition eligibility upon a further test of deferrability.

In excluding from coverage such deferrable operations the state statute conflicts with the federal act. This conclusion is consistent with the opinion of HEW which was communicated to the Governor of New York in a letter dated 7. the day before he signed the contested provision into law.

That letter reads in pertinent part:

Section 3 of the law, amending section 365-a of the Social Services Law would significantly limit surgical benefits reimbursed under Medicaid. The surgical procedures so limited are provided as "inpatient hospital services" or "physicians services" which are both mandatory services under a state Medicaid program. Under Medicaid regulations "inpatient hospital services" are defined as "those items and services ordinarily furnished by the hospital for the care and treatment of inpatients * * *" (emphasis supplied). "Physician services" are defined in the Medicaid regulations as "services provided, within the scope of practice of his profession as defined by State law * * *". Certain surgical procedures -- outside the scope of the limiting amendment -- would be 'ordinarily provided' or still within general state defined physician practices. Accordingly, some surgical procedures and physician services outside the scope of the New York amendment must be provided to Medicaid recipients. 8.

Letter of Bernice L. Bernstein, Regional

Director for Region II, Department
of Health, Education, and Welfare,
to the Governor of the State of New
York, dated March 29, 1976, at 2
(citations and footnotes omitted).

Defendants attempt to minimize the conflict between the federal and state provisions by arguing that the term "essential function" was intended to mean any function necessary to "the patient's ability to function adequately in our society". Defendants' Memorandum, filed Aug. 23, 1976, at 22-23. But, the regulation implementing paragraph (c) of §365-a(5), 10 NYCRR §85.3, gives no indication that the term is actually being applied in such an expansive manner. Moreover, clearly implicit in the language of paragraph (c) is that Medicaid coverage does not extend to some medically warranted operations where deferral may cause significant -- although something less than "severe" -- pain. In any event, no matter how expansively the term "essential function" is interpreted, paragraph (c) still denies reimbursement for certain operations solely on the ground of deferrability, a basis for denial which cannot be reconciled with the federal requirement that Medicaid coverage extend to "physicians' services furnished by a physician".

F. The Need For A Preliminary Injunction.

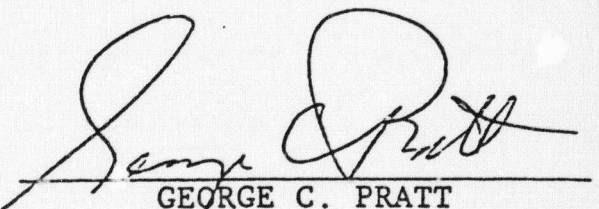
A plaintiff may obtain a preliminary injunction where it makes a clear showing that there is a likelihood of success on the merits and irreparable injury. E.g., Diversified Mortgage Investors v. United States Life Title Insurance Co. of New York, No. 75-7428, slip op. at 4544 (CA2 June 30, 1976); Checker Motors Corp. v. Chrysler Corp., 405 F2d 319, 323 (CA2 1969). For the reasons discussed above, the court concludes that the Medical Society will probably succeed in establishing that the scheme for reimbursement of surgical procedures established by paragraphs (a), (b), (c) and (e) of NYSSL §365-a(5) violates the Social Security Act. Moreover, obviously and as illustrated by the cases of Doe and Ortega, without Medicaid assistance persons eligible for it often cannot obtain appropriate surgical care and thus must continue to suffer the symptomology and risks which warrant such care. Consequently, the court concludes that the "irreparable injury" requirement has been met. Accordingly, a preliminary injunction must issue against the enforcement of paragraphs (a), (b), (c) and (e) and all regulations promulgated thereunder.

In concluding, the court notes its awareness of the serious financial impact that the order issued pursuant to

this memorandum may have on the State of New York. The court also realizes that one of the objectives of paragraphs (a), (b), (c) and (e) was to reduce unwarranted surgical procedures reimbursed under New York's Medicaid program -- an objective which clearly is consistent with the Social Security Act. But a second objective of these amendments was to reduce the types of medically indicated surgical procedures to be reimbursed under the Medicaid program, and, in attempting to implement this objective, the provisions appear clearly to have fallen short of the Act's broad coverage for "physicians' services". Under the supremacy clause, a conflict between the state's amendments and the requirements of the federal act must be resolved in favor of the latter. Whether the federal requirement for coverage is excessively broad is a question of policy that only the Congress may consider.

Settle order on notice.

Dated: Westbury, New York
January 18, 1977


GEORGE C. PRATT
U. S. DISTRICT JUDGE

F O O T N O T E S

1./ All factual findings expressed herein have been made solely for the purpose of deciding the instant motion. Since the parties agreed that an evidentiary hearing was unnecessary, these findings are based on the depositions and affidavits.

2./ In view of the foregoing, the possible alternative jurisdictional basis alleged under 28 USC §1331 need not be considered. Cf. Moore v. Betit, 511 F2d 1004 (CA2 1975); Aitchison v. Berger, 404 F Supp 1137 (SDNY 1975); Eass v. Rockefeller, 331 F Supp 945 (SDNY 1971), appeal dismissed as moot, 464 F2d 1300 (CA2 1971); Yanez v. Jones, 361 F Supp 701, 706 (D Utah 1973); but see Kheel v. Port of New York Authority, 457 F2d 46 (CA2 1972); Rosado v. Wyman, 414 F2d 170 (CA2 1969), rev'd on other grounds, 397 US 397 (1970).

3./ The complaint was filed on August 5, 1976, one week prior to the effective date of the repeal of 28 USC §2281 and the amendment of 28 USC §2284, Pub. L. No. 94-381 (Aug. 12, 1976), and therefore would require a three-judge court if the constitutional issues were to be reached.

4./ 42 USC §§1396a(a)(13)(B) and (C) provide:

A state plan for medical assistance must
* * * provide * * *

(B) in the case of individuals receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI, or part A of subchapter IV of this chapter, or with respect to whom supplemental security income benefits are being paid under subchapter XVI of this chapter, for the inclusion of at least the care and services listed in clauses (1) through (5) of section 1396d(a) of this title, and

(C) in the case of individuals not included under subparagraph (B) for the inclusion of at least--

(i) the care and services listed in clauses (1) through (5) of section 1396d(a) of this title or

(ii)(I) the care and services listed in any 7 of the clauses numbered (1) through (16) of such section and (II) in the event the care and services provided under the State plan include hospital or skilled nursing facility services, physicians' services to an individual in a hospital or skilled nursing facility during any period he is receiving hospital services from such hospital or skilled nursing facility services from such facility * * *.

5./ Defendants argue that since Doe and Ortega have not exhausted their administrative remedies the facts of their cases may not be considered here. The regulations implementing NYSSL §365-a(5), however, make an individual's ability to obtain a "determination of coverability" contingent upon the initiation of a written request by his surgeon. E.g., 10 NYCRR §85.3(c). Moreover, the regulations provide for the appeal of a "determination of non-coverability" by the proposing surgeon, not by the patient himself. E.g., 10 NYCRR §85.3(h). The failure of a surgeon either to apply for a determination of coverability, or to appeal a determination of non-coverability on behalf of his patient, should not be deemed a failure of the patient to exhaust his administrative remedies. In such circumstances the patient has done all he can within the power granted to him by the state's administrative procedures.

6./ In addition to the evidence relating to the medical circumstances of plaintiff Ortega, the record contains evidence of numerous other medical conditions warranting surgical treatment, coverage of which is mandated by the Social Security Act but denied by NYSSL §365-a(5). Some examples are certain cases of bleeding hemorrhoids, lipomas of the vulva, and umbilical hernias.

7./ On approving Chapter 76, the Governor stated:

This bill is a substantially amended version of my original Budget Bill submitted both in the Special Session last year and again early in this Session. It has

been changed by the Legislature in virtually every major respect, and as a result, both the Commissioner of Health and the Acting Commissioner of Social Services have advised me that they have serious reservations about the bill. In addition, the Regional Director (Region II) of the Department of Health, Education and Welfare has written to express the Department's concern over certain provisions in the bill.

The expenditure savings projected under the bill are essential to achieve a balanced budget, and because of the urgent need to present such a budget for the State of New York, I must sign this measure into law. I do so, however, with reluctance and with a determination to put before the Legislature in the near future a number of proposed changes designed to meet the objections raised by the Departments of Health and Social Services and to insure that the Medicaid program in this State can be effectively and fairly administered.

Session Law News of New York
(McKinney May 10, 1976) at A-251.

8./ The letter reasons, as have plaintiffs, that the state statute's denial of coverage for certain surgical procedures violates the Social Security Act not only because these procedures constitute "physicians' services" but also because they constitute "inpatient hospital services", coverage of which is also mandated by the Act. At present there is no need to address this additional argument.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- - - - - x
THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE
DOE,

DOCKET NO. 76 C 1443

Plaintiffs,

- against -

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P.
WHALEN, M.D., as Commissioner of the
Department of Health of the State of
New York,

Defendants.

- - - - - x
PRATT, J:

ORDER
AMENDING
MEMORANDUM AND ORDER
OF JANUARY 18, 1977

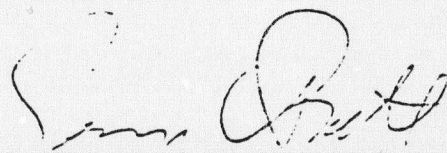
On the court's own motion, the memorandum and
order dated January 18, 1977, is hereby amended as follows:

1. In the fifth line of the first complete para-
graph of page 2, the name "Richard" is amended to read
"Ricarda".

2. In the fifth line from the bottom of page 26,
the word "where" is amended to read "unless".

SO ORDERED.

Dated: Westbury, New York
January 20, 1977



GEORGE C. PRATT
U. S. DISTRICT JUDGE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
THE MEDICAL SOCIETY OF THE STATE OF :
NEW YORK, a New York not-for-profit :
corporation, MORTON M. KOFF, M.D., :
MILTON ROSENBERG, M.D., and JANE DOE, :
:

Plaintiffs,

-against-

PHILIP TOIA, as Commissioner of the :
Department of Social Services of the :
State of New York and ROBERT P. WHALEN, :
M.D., as Commissioner of the Department :
of Health of the State of New York, :
:

Defendants.

: Index No. 76 Civ. 1976

: ORDER TO SHOW CAUSE

-----x
Upon the annexed affidavits of Morton M. Koff, M.D.,
Milton Rosenberg, M.D. and of Charles P. Sifton, sworn to on
the 2nd day of August, 1976, and the summons and complaint
herein, it is hereby

ORDERED, that the defendants Commissioner of Social
Services and Commissioner of Health show cause before the
Honorable JUDGE, a judge of this Court, in Room 6
at the United States Courthouse, 225 Cadman Plaza East, Brook-
lyn, New York, on the 11 day of August, 1976 at 10 A.M.,
or as soon thereafter as counsel may be heard, why an order
should not be entered staying the effective date of Sections 3
and 4 of Chapter 76 of the Laws of New York, 1976 and enjoining
said defendants pending the disposition of this action from
enforcing or implementing said Sections, and any regulations or
instructions issued pursuant thereto; and it is further

ORDERED, that service of a copy of this order and the annexed affidavits, the summons, complaint and memorandum of law personally on the defendants or their attorneys on or before shall be sufficient service of the within order.

Dated: Brooklyn, New York
August 5, 1976

SO ORDERED:

United States District Judge

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE,

Plaintiffs,

-against-

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P. WHALEN,
M.D., as Commissioner of the Department
of Health of the State of New York,

Defendants.

:
:
: Index No. 76 Civ.
:

: AFFIDAVIT IN SUPPORT
: OF APPLICATION FOR
: ORDER TO SHOW CAUSE

-----x
STATE OF NEW YORK)
) ss:
COUNTY OF NASSAU)

MORTON M. KOFF, being duly sworn, deposes and says:

1. I am a doctor of medicine, duly licensed to practice under the laws of the State of New York and one of the plaintiffs herein. I make this affidavit in support of the application of all the plaintiffs herein for an order directing the defendants Commissioner of Social Services and Commissioner of Health to show cause why an order should not be entered herein staying the effective date of Sections 3 and 4 of Chapter 76 of the Laws of New York, 1976 and enjoining said defendants pending the disposition of this action from enforcing or implementing those Sections and the regulations or instructions issued pursuant thereto.

2. The grounds for plaintiffs' application are that Sections 3 and 4 of Chapter 76 and the regulations issued

pursuant thereto eliminate the availability of reimbursement for certain types of deferrable surgical procedures for persons otherwise qualified for such procedures under the provisions of Title XIX of the Federal Social Security Law, 42 U.S.C. §§1396 et seq. ("Medicaid") in violation of the Federal statute.

As a result the State statute unlawfully and unconstitutionally interferes with a physician's right to practice medicine according to his best medical judgment and with the rights of Medicaid patients to be treated according to the best medical judgment of his or her attending physician to the irreparable injury of both patient and physician.

3. As set forth in the Complaint herein, I am a member of plaintiff The Medical Society of the State of New York (the "Medical Society"). In addition, I am a member of the Nassau County Medical Society and the American Medical Association. My specialization in the practice of medicine is family medicine and I maintain a private office at 801 East Park Avenue, Long Beach, New York. In the course of practicing my profession, I have occasion to treat patients covered by Medicaid, as well as patients not covered by that program, and to recommend surgical procedures with respect to such patients.

4. I have recently read Chapter 76 of the Laws of New York, 1976, a copy of which is annexed hereto as Exhibit A, together with the currently effective regulations of the Department of Health and a draft Administrative Letter of the Department of Social Services proposed to be promulgated pursuant thereto, copies of which are annexed hereto as Exhibits B and C, respectively. The statute, regulations and Administrative Letter provide, as here relevant, that the

defendant Commissioner of Social Services will no longer certify for payment under Medicaid any claims for deferrable in-patient surgical procedures or services of a physician related thereto except when two physicians certify to the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function or cause severe pain to the patient or except when defendant Commissioner of Health permits such procedures and services on the basis of "medical risks." In the event that such surgical procedures cannot be compensated pursuant to Medicaid, most, if not all, Medicaid patients will be unable to have such procedures performed and physicians like myself will be unable to carry them out except on an ad hoc charitable basis.

5. As set forth in the Complaint herein, the federal government currently provides monies to states for the provision of medical assistance to qualified low income and indigent persons pursuant to a joint federal-state program known as Medicaid governed by Title XIX of the Social Security Act, 42 U.S.C. §1396 et seq. and the regulations promulgated thereunder.

6. The Medicaid Act requires that any state which accepts monies from the federal government pursuant to the Medicaid program have in effect a state plan providing that qualified low income and indigent persons be entitled to payment for in-patient hospital services and physicians' services furnished by licensed practitioners within the scope of their practice, as defined by state law, to their patients. 42 U.S.C. §1396d(a)(1) and (5). Federal regulations issued pursuant to the Medicaid statute provide that the state plan

must cover "in-patient hospital services" defined as "those items and services ordinarily furnished by the hospital for the care and treatment of in-patients provided under the direction of a physician" as well as "physicians' services" defined as "those services provided, within the scope of his practice as defined by state law, by or under the personal supervision of an individual licensed under state law to practice medicine or osteopathy." 45 C.F.R. §249.10(b)(1) and (b)(5). Federal regulations further provide that:

"The State may not arbitrarily deny or reduce the amount, duration or scope of such services for an otherwise eligible individual solely because of the diagnosis, type of illness or condition." 45 C.F.R. §249.10(a)(5)(i).

7. New York State has, since 1966, had in effect a state Medicaid program purporting to comply with all federal requirements and authorizing and directing the acceptance of federal funds under the federal Medicaid program and their disbursement to qualified persons for medical assistance certified as proper for payment by the Department of Social Services. New York Social Services Law, Title 11. Included in such program is provision for certification and payment for surgical procedures and physicians' services "necessary to prevent, diagnose, correct or cure conditions...that cause acute suffering, endanger life, result in illness or infirmity, interfere with...[the patient's] capacity for normal activity, or threaten some significant handicap...." Social Services Law §365-a.

8. On March 30, 1976, the Governor of New York State signed into law Chapter 76 amending Section 365-a of the Social Services Law significantly limiting the authority of defendant

Toia to certify for payment certain surgical procedures theretofore paid under the state program. Thus, Section 3 of the new law, after directing that "medical assistance shall not include any in-patient surgical procedures or any care, services or supplies related to such surgery other than those authorized by this subdivision," eliminated all deferrable surgery other than surgery specified by the defendant Commissioner of Health on the basis of "medical risk" and surgery as to which two doctors certify that its deferral for six months or more may jeopardize life or essential function or cause severe pain.

9. Pursuant to such authority, defendants Toia and Whalen have promulgated regulations and a draft Administrative Letter eliminating compensation under Medicaid for deferrable surgery except in certain specified cases, including abortions and vasectomies, and except where two doctors certify that such surgery cannot be deferred for six months or more without jeopardizing life or essential function or causing severe pain.

10. Prior to enactment of the statute and regulations, the U.S. Department of Health, Education and Welfare wrote a letter dated February 27, 1976 to Mr. Stephen Berger, then Commissioner of the New York State Department of Social Services, and a letter dated March 29, 1976 to the Honorable Hugh L. Carey, Governor of the State of New York, describing the conflicts between the proposed state statute and Federal Medicaid statutes, and pointing out the violations of Federal law which would occur if the State of New York enacted Chapter 76 in its present form. See Exhibits D and E attached hereto.

11. In the course of practicing my profession and within the scope of my practice under state law, I and numerous other members of the Medical Society have occasion to recommend and to perform surgery for patients qualified for Medicaid both on an in-patient and out-patient basis in numerous situations not excepted by defendant Commissioner of Health in which two doctors could not be expected to certify that the surgery could not be deferred for six months or more without jeopardizing life or essential function or causing severe pain. Besides being generally available to other non-Medicaid patients as part of the ordinary practice of medicine within New York State, these surgical procedures are also medically necessary and desired by the patients for perfectly legitimate reasons, including the alleviation of continued moderate pain, the elimination of serious emotional and psychological trauma and, on occasion, difficulties in obtaining gainful employment.

Following are examples of disorders requiring surgery for which such surgery will not be available to Medicaid patients:

(1) bleeding hemorrhoids -- it is not uncommon that a patient, including Medicaid patients, will be suffering from hemorrhoids that are frequently bleeding and staining the patient's clothing, while causing only minor physical discomfort. Because deferral of surgery to correct this disorder would not jeopardize life or essential function, or cause severe pain, the surgery would not be covered for Medicaid patients. Whereas I would normally admit such a patient to the hospital for the necessary surgery and the hospital would

ordinarily provide the necessary services in support of surgery, I will be unable to admit a Medicaid patient having this type of disorder because the surgery and support services will not be covered by Medicaid.

(2) lipoma or other benign tumor of the vulva -- this disorder does not ordinarily cause pain except during intercourse, and not necessarily then if performed in a position which alleviates the pressure on the tumor. Since deferral of surgery to correct the disorder would not jeopardize life or essential function and would not cause severe pain, such surgery would not be covered by Medicaid. Since a patient, including a Medicaid patient, suffering from the above-mentioned disorder frequently experiences serious emotional trauma resulting from the difficulty surrounding sexual relations and the restricted nature of such relations, I would normally admit such patients to the hospital for surgery and the hospital would ordinarily furnish the supportive services. However, since surgery for this disorder would not be covered under Medicaid, I will be unable to admit Medicaid patients suffering from this disorder to the hospital, and such patients will be unable to obtain relief from this disorder. Thus, even though surgery is medically necessary and will be provided to patients who are fortunate enough not to have to rely on Medicaid for health care, such surgery will not be available to Medicaid patients.

(3) umbilical hernia -- symptomatic of this disorder is a large lump located in a patient's waist-line area. It does not ordinarily cause severe pain. Because deferral of corrective surgery for six months would not threaten life or

essential function, or cause severe pain, it would not be covered under Medicaid. Such hernias are, however, frequently disfiguring and the cause of a great deal of mental anguish and emotional trauma for the patient. Depending on the size of the hernia and the resulting disfigurement and discomfort, I would normally admit such a patient to the hospital for surgery and the hospital would ordinarily provide the appropriate services. However, since the required surgery would not be covered under the new Health Department regulations, I will be unable to admit Medicaid patients requiring it and they will be unable to obtain relief.

(4) joint cartilage surgery -- deferral of surgery concerning this disorder for six months would not ordinarily threaten life or essential function, or cause severe pain; thus it would not be covered by Medicaid. However, this disorder, if uncorrected over a period of several years, will often develop into a painful form of arthritis. In order to prevent the development of such arthritis and depending upon the diagnosis of the particular case, I would in many instances admit the patient for surgery and the hospital would ordinarily provide the required services prior to the development of pain. But, because the surgery is no longer covered under the new regulations, I will be unable to admit Medicaid patients until such time as the disorder has developed to the point that it "threatens to cause severe pain" in the form of arthritis. The regulations seem particularly arbitrary and unfair in cases of this type, because the State will pay the cost of the surgery at a later date when the disorder has developed into the arthritic stage. For disorders of this type, then, the new

regulations do not even save the State money; they merely postpone the date of payment. In the meantime, the Medicaid patient is forced to suffer the disorder and to allow the painful arthritis to develop.

12. In addition to the outright deprivation of surgical procedures where "severe pain" is clearly not involved, the standards with respect to deferrable surgery are unworkable in those cases where substantial pain is involved and the physician is required by Chapter 76 to make a judgment as to whether the pain is "severe," a term with no accepted medical meaning. Whether pain is severe, moderate, minor or non-existent is a completely subjective determination which can be made only by the patient. My experience, and that of others in the medical profession, has been that there are many instances in which patients suffering the same disorder experience different levels of pain due to the varying pain thresholds bestowed upon them by nature. An additional factor is the subtle, but no less real, part that an individual's mental perception of himself and a particular disorder plays in determining the level of pain outwardly manifested by that individual. To require a physician to determine whether a Medicaid patient can obtain surgery for a particular non-acute disorder based upon such a vague, arbitrary and indeterminable standard as "severe pain" imposes an intolerable compliance burden upon the medical profession.

13. No less difficult to determine is the meaning of "essential function." For example, some physicians, including myself, will conclude that a benign tumor of the vulva which prevents a patient from being able to engage freely in sexual

relations does not jeopardize "essential function" and, thus, is not covered by Medicaid, since sexual reproduction may still occur. Other physicians may conclude that free and unrestricted sexual relations are an "essential function" that is jeopardized by such a disorder, and, thus, is covered by Medicaid. Consequently, whether surgery to correct this disorder will be provided to a Medicaid patient will hinge upon the attitude of the physician the patient happens to visit and the attitude of the physician who happens to be the Health Department's designee charged with determining coverability concerning that patient, rather than upon a realistic standard of medical necessity uniformly applied to all Medicaid patients. There are other such disorders which will pose this kind of definitional problem.

14. I am also concerned with the utter lack of meaning contained in that portion of Section 3 of Chapter 76 which permits defendant Commissioner of Health to allow reimbursement for specified surgical procedures on the basis of "medical risk." Because the Section fails to specify the risk referred to, i.e., risk of severe pain, threat to life or some lesser risk resulting from increased complications in performing later surgery, the Section constitutes a totally arbitrary delegation of legislative power to the Commissioner of Health. In fact, as may be seen from the Commissioner's regulations issued pursuant to the Section, the language has been used in a completely arbitrary and political fashion to except vasectomies and abortions from the requirements of the statute (see Appendix B attached hereto, Section 85.2(a)(4)). In my view, there is no difference in terms of medical risk or in any other

terms between the medical need for surgery in the case of abortions, vasectomies and the other excluded complaints referred to in Appendix B attached hereto, Section 85.3. Indeed, it is apparent that there has been simply an arbitrary discrimination on totally political grounds between these complaints.

15. Section 85.3 of the Health Commissioner's regulations require that a pre-admission determination of coverability be made by a person designated by the Health Department with respect to non-emergency surgery for Medicaid patients. The regulations provide that a determination of coverability can be made by a physician or non-physician, although a determination of non-coverability can only be made by a physician. This has resulted in non-physicians being designated by the Health Department to make the initial determination, which, if negative, must be referred to a designated physician for a decision as to non-coverability. The regulations provide that the patient's physician must submit details concerning the patient's illness and the physician's diagnosis to the non-physician and physician designees of the Health Department. Such disclosure will necessarily relate to highly personal and private matters, oftentimes involving the most intimate aspects of life, such as sexual intercourse and related circumstances. Traditionally, the doctor/patient relationship has protected the confidentiality of information concerning a patient's physical ailments and his physician's prescription for the ailments. However, under Chapter 76, the constitutional rights of privacy of Medicaid patients and their physicians will be seriously

*Confidential
Sub. 1*

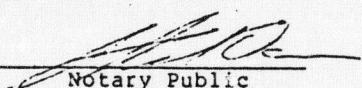
eroded, and the doctor/patient relationship will cease to have meaning for the poor.

16. In short, the requirements of Chapter 76 and the regulations and rules promulgated pursuant thereto by the Health Department and the Social Services Department are disastrous for the medical profession and for Medicaid patients because there are a whole host of disorders that require surgery and are medically necessary, thus qualifying for medical assistance under Federal Medicaid standards, but which do not qualify for Medicaid under the above-mentioned New York statute and regulations. In addition, the statute and regulations set forth standards for coverability which are arbitrary, vague, and incapable of determination by those physicians who are directed to comply with the standards or by those physicians who are empowered to enforce the standards.

WHEREFORE, for the reasons set forth herein and in the accompanying memorandum of plaintiffs, I respectfully request this Court to enter an order directing the defendants Commissioner of Social Services and Commissioner of Health to show cause why an order should not be entered enjoining said defendants from enforcing or implementing certain provisions of the recently enacted Chapter 76 of the Laws of New York, 1976, and regulations issued pursuant thereto.

Sworn to before me this

2 day of ^{August} ~~July~~, 1976


Notary Public

STUART DAVIS
NOTARY PUBLIC, State of New York
No. 20-0132240
Qualified in Nassau County
Commission Expires March 30, 1977

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Exhibit A

Medical Assistance and Home Relief Programs—
Expenditures—Emergency Controls

Memoranda relating to this chapter, see pages A-238, A-251.

CHAPTER 76

An Act to amend the social services law, the public health law and the education law, in relation to emergency controls of expenditures under the medical assistance program and the home relief program.

Approved March 30, 1976, effective as provided in section 18.

Passed on message of necessity. See Const. art. IX, § 2(b)(2), and McKinney's Legislative Law § 44.

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. New York has a long, proud history of providing generously for people in need, and the legislature has no intention of forsaking that history. It is recognized, however, that the state and local governments are facing emergency fiscal crises of staggering proportions, and cannot continue to support the scope and level of assistance, care and services the cost of which has sharply escalated in recent years. In order to assure that funds are available for essential and critical medical services, that basic medical necessities for the needy are provided, and that critical assistance, care and health services will be available to all of the people, the legislature, pursuant to the constitution of the state of New York, hereby finds and declares that a state of emergency exists and hereby confers emergency powers on the governor to take such steps as are necessary to implement the following controls on medical assistance and public assistance expenditures.

§ 2. Section three hundred sixty-five-a of the social services law is hereby amended by adding thereto a new subdivision, to be subdivision four, to read as follows:

4. Any inconsistent provision of law notwithstanding, medical assistance shall not include, unless required by federal law and regulation as a condition of qualifying for federal financial participation in the medicaid program drugs which may be dispensed without a prescription as required by section sixty-eight hundred ten of the education law; provided, however, that the state commissioner of health may by regulation specify certain of such drugs which may be reimbursed as an item of medical assistance in accordance with the price schedule established by such commissioner.

§ 3. Section three hundred sixty-five-a of such law is hereby amended by adding thereto a new subdivision, to be subdivision five, to read as follows:

5. (a) Medical assistance shall include surgical benefits for emergency or urgent surgery for the alleviation of severe pain, for immediate diagnosis or treatment of conditions which threaten disability or death if not promptly diagnosed or treated.

(b) Medical assistance shall include surgical benefits for certain surgical procedures which meet standards for surgical intervention, as established by the state commissioner of health on the basis of

medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with such surgical intervention.

(c) Medical assistance shall include surgical benefits for other deferrable surgical procedures specified by the state commissioner of health, based on the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function, or cause severe pain; provided, however, such procedures shall be included in the case of in-patient surgery, except surgery authorized pursuant to paragraph (a) of this subdivision, only when a second written opinion is obtained from a physician, or as otherwise prescribed, in accordance with regulations established by the state commissioner of health, that such surgery should not be deferred.

1 day pre-operative
(d) Medical assistance shall include a maximum of one patient day of pre-operative hospital care for surgery authorized by paragraphs (b) or (c) of this subdivision; provided, however, that with respect to specific surgical procedures which the state commissioner of health has identified as requiring more than one patient day of pre-operative care, medical assistance shall include such longer maximum period of pre-operative care as such commissioner has identified as necessary.

(e) Medical assistance shall not include any in-patient surgical procedures or any care, services or supplies related to such surgery other than those authorized by this subdivision.

§ 4. Paragraph (b) of subdivision two of section three hundred sixty-five-a of such law, as amended by chapter six hundred ninety-four of the laws of nineteen hundred seventy-two, is hereby amended to read as follows:

(b) care, treatment, maintenance and nursing services in hospitals, nursing homes that qualify as providers in the medicare program pursuant to title XVIII of the federal social security act,¹ infirmaries or other eligible medical institutions, and health-related care and services in intermediate care facilities, while operated in compliance with applicable provisions of this chapter, the public health law, the mental hygiene law and other laws; including any provision thereof requiring an operating certificate or license, or where such facilities are not conveniently accessible, in hospitals located without the state; provided, however, that care, treatment, maintenance and nursing services in nursing homes, including those operated by the state department of mental hygiene or any other state department or agency, shall be limited to one hundred days during any spell of illness for persons who are receiving or are eligible for medical assistance under provisions of subparagraph four of paragraph (a) of subdivision one of section three hundred sixty-six of this chapter, plus, with the prior approval of the commissioner of health upon the recommendation of the appropriate medical director, or with the prior approval of the commissioner of mental hygiene in the case of nursing homes operated by the state department of mental hygiene, such additional periods of time as may be necessary in cases of clear need for nursing services; provided, further, that in-patient care, services and supplies in a general hospital shall not exceed such standards as the commissioner of health shall promulgate but in no case greater than twenty days per spell of illness during which all or any part of the cost of such care, services

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and supplies are claimed as an item of medical assistance, unless it shall have been determined in accordance with procedures and criteria established by such commissioner that a further identifiable period of in-patient general hospital care is required for particular patients to preserve life or to prevent substantial risks of continuing disability.

¹ 42 U.S.C.A., § 1395 et seq.

§ 5. Paragraph (b) of subdivision two of section three hundred sixty-six of such law, as amended by chapter thirty-two of the laws of nineteen hundred sixty-eight, is hereby amended to read as follows:

(b) In establishing standards for determining eligibility for and amount of such assistance, the department shall take into account only such income and resources, in accordance with federal requirements, as are available to the applicant or recipient and as would not be required to be disregarded or set aside for future needs, and there shall be a reasonable evaluation of any such income or resources. There shall not be taken into consideration the financial responsibility of any individual for any applicant or recipient of assistance under this title unless such applicant or recipient is such individual's spouse or such individual's child who is under twenty-one. In the application of standards of eligibility with respect to income, costs incurred for medical care, whether in the form of insurance premiums or otherwise, shall be taken into account. Any person who is eligible for, or reasonably appears to meet the criteria of eligibility for, benefits under title XVIII of the federal social security act shall be required to apply for and fully utilize such benefits in accordance with this chapter.

§ 6. The opening paragraph of section three hundred sixty-seven of such law is hereby designated to be subdivision one thereof, and such section is hereby amended by adding thereto a new subdivision, to be subdivision two, to read as follows:

2. Notwithstanding any inconsistent provision of law, the social services official responsible for authorizing hospital or health related services shall withhold payment for such services upon the certification of the commissioner of health that such care is inappropriate or unnecessary.

§ 7. Subdivisions four through six of section three hundred sixty-seven-a of such law are hereby renumbered to be subdivisions five through seven, respectively, and a new subdivision, to be subdivision four, is hereby added thereto, to read as follows:

4. No social services district shall make final payments pursuant to title XIX of the federal social security act¹ for benefits available under title XVIII of such act without documentation that title XVIII claims have been filed and denied.

¹ 42 U.S.C.A., § 1396 et seq.

§ 8. Subdivisions one and two of section twenty-eight hundred three of the public health law, subdivision one having been amended by chapter six hundred forty-nine of the laws of nineteen hundred seventy-five and subdivision two having been amended by chapter nine hundred fifty-six of the laws of nineteen hundred seventy-four, are hereby amended to read, respectively, as follows:

1. a. (a) The commissioner shall have the power to inquire into the operation of hospitals and home health agencies and to conduct periodic inspections of facilities with respect to the fitness and adequacy of the premises, equipment, personnel, rules and by-laws, standards of medical care, hospital service, including health-related service,

home health service, system of accounts, records, and the adequacy of financial resources and sources of future revenues. The commissioner or persons designated by him shall each year conduct two or more inspections of each residential health care facility, at least one of which shall be unannounced, to determine the adequacy of care being rendered. Any employee of the department who gives or causes to be given advance notice of such unannounced inspection to any unauthorized person shall, in addition to any other penalty provided by law, be suspended by the commissioner from all duties without pay for at least five days or for such greater period of time as the commissioner shall determine. Any such suspension shall be made by the commissioner in accordance with all other applicable provisions of law.

b. (b) The purpose of such inspections shall be to determine compliance by residential health care facilities with statutes, and with regulations promulgated under the provisions of those statutes, governing minimum standards of construction, quality and adequacy of care, rights of patients, rates of payment and reimbursement. At least one such inspection each year shall include, but shall not be limited to, full on-site examination and audit of the medical, nursing care, dietary, social services and financial records of the facility. The on-site audits of financial records shall encompass the immediately preceding complete fiscal year of the residential health care facility, and shall not be conducted in any instance in which an audit of such fiscal year shall already have been completed as part of a previous inspection.

c. (c) The commissioner shall promulgate and publish uniform criteria for the evaluation of residential health care facilities with respect to their compliance with the standards set forth in this section, as indicated by the results of the inspections conducted pursuant to the provisions of this section. Such criteria shall include a detailed listing of the types, and degree of severity or unacceptability, of deficiencies which inspections might indicate, and shall also indicate areas of care and performance in which residential health care facilities notably and significantly exceed required minimum standards. In promulgating such criteria, the commissioner shall devise a system of rating residential health care facilities in accordance with the deficiencies and areas of significantly high care and performance which the reports of inspection shall have indicated. Such system shall include no less than five specific rating categories. The rating assigned to each residential health care facility on the basis of its immediately prior inspection shall be deemed a part of the results and findings of that inspection, and shall be required by the commissioner to be posted conspicuously within the residential health care facility to which it applies. A facility may appeal the assignment of a particular rating to the commissioner within twenty days after notice of its assignment. The results and findings of any prior inspections, and any penalties thereby assessed, which have not been previously appealed and overruled, shall not be subject to review.

(d) Notwithstanding any inconsistent provision of law, the commissioner shall, not later than July first, nineteen hundred seventy-six, determine the necessity and appropriateness of care and services provided by hospitals and home health agencies to individual patients. In making such determinations the commissioner may function through department personnel or other authorized representatives. The hospitals shall provide such information, facilities and services as may be required by the commissioner to make such determinations. The commissioner, in implementing this paragraph, shall adopt necessary rules and regulations including but not limited to those for determining

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the necessity of admission, controlling the length of stay, the provision of surgery and other services, and the methods and procedures for making such determinations. The commissioner shall certify to the social services officials responsible for authorized hospital or health related services that payment for inappropriate or unnecessary care shall be withheld.

2. The council, by a majority vote of its members, shall adopt and amend rules and regulations, subject to the approval of the commissioner, to effectuate the provisions and purposes of this article, including, but not limited to (a) the establishment of requirements for a uniform statewide system of reports and audits relating to the quality of medical and physical care provided, hospital utilization and costs in accordance with section twenty-eight hundred three-b, (b) establishment by the department of schedules of rates, payments, reimbursements, grants and other charges for hospital, health-related services and home health services as provided in section two thousand eight hundred seven (c) standards and procedures relating to hospital operating certificates and home health certificates of approval, provided however, that the council shall establish minimum acceptable standards and procedures equal to the standards and procedures which federal law and regulation require for hospitals to qualify as providers pursuant to titles XVIII and XIX of the federal social security act. The existing state standards and procedures in effect on the date that this section becomes effective shall be deemed to constitute maximum standards and procedures for purposes of limiting medical assistance reimbursement pursuant to the social services law. Such standards and procedures may thereafter be changed or added to by the council only upon the recommendation of the commissioner. For the purposes of ensuring that the health and safety of the residents of hospitals are not endangered, the council may promulgate changes in the minimum acceptable standards and procedures referred to herein upon recommendation of the commissioner. For the purposes of orderly implementation of this subdivision, the commissioner of health may grant waivers to maximum reimbursable standards to expire no later than March thirty-first, nineteen hundred seventy-eight and (d) the establishment of a system of accounts and cost findings to be used by hospitals, including a classification of such hospitals and the prescription of a system of accounts and cost finding for each class in accordance with section twenty-eight hundred three-b. The commissioner may propose rules and regulations and amendments thereto for consideration by the council.

§ 9. Section twenty-eight hundred six of such law is hereby amended by adding thereto a new subdivision, to be subdivision five, to read as follows:

5. (a) Notwithstanding the provisions of subdivisions two through four of this section, the commissioner shall suspend, limit or revoke a general hospital operating certificate, after taking into consideration the total number of beds necessary to meet the public need, and the availability of facilities or services such as preadmission, ambulatory, home care or other services which may serve as alternatives or substitutes for the whole or any part of any such hospital facility, and after finding that suspending, limiting, or revoking the operating certi-

ificate of such facility would be within the public interest in order to conserve health resources by restricting the number of beds and/or the level of services to those which are actually needed.

(b) Whenever any finding as described in paragraph (a) of this subdivision is under consideration with respect to any particular facility, the commissioner shall cause to be published, in a newspaper of general circulation in the geographic area of the facility at least thirty days prior to making such a finding an announcement that such a finding is under consideration and an address to which interested persons can write to make their views known. The commissioner shall take all public comments into consideration in making such a finding.

(c) The commissioner shall, upon making any finding described in paragraph (a) of this subdivision with respect to any facility, cause such facility and the appropriate health systems agency to be notified of the finding at least thirty days in advance of taking the proposed action to revoke, suspend or limit the facility's operating certificate. Upon receipt of any such notification and before the expiration of the thirty days or such longer period as may be specified in the notice, the facility or the appropriate health systems agency may request a public hearing to be held in the county in which the hospital is located. In no event shall the revocation, suspension or limitation take effect prior to the thirtieth day after the date of the notice, or prior to the effective date specified in the notice or prior to the date of the hearing decision, whichever is later.

(d) Except as otherwise provided by law, all appeals from a finding of the commissioner made pursuant to paragraph (a) of this subdivision shall be directly to the appellate division of the supreme court in the third department. Except as otherwise expressly provided by law, such appeals shall have preference over all issues in all courts.

§ 10. Subdivision one of section twenty-eight hundred seven of such law, as amended by chapter nine hundred eighteen of the laws of nineteen hundred seventy-two, is hereby amended to read as follows:

1. No government agency and no corporation organized and operated in accordance with article nine-c of the insurance law shall purchase, pay for or make reimbursement or grants-in-aid for any hospital or health-related service, including home health service, unless, at the time the service was provided, the hospital possessed a valid operating certificate authorizing such service or in the case of a home health agency a valid certificate of approval. No government agency shall purchase, pay for or make reimbursement or grants-in-aid for any hospital or health related service, including home health services that have been determined by the commissioner of health to be unnecessary or inappropriate under section twenty-eight hundred three of this title.

§ 11. Subdivision two of section twenty-eight hundred seven of such law, as amended by chapter nine hundred eighteen of the laws of nineteen hundred seventy-two, is hereby amended to read as follows:

2. (a) Payments for hospital service and health-related service, including home health service, made by government agencies or corporations organized and operating in accordance with article nine-c of the insurance law¹ shall be at rates approved by the state director of the budget in the case of government agencies and approved by the super-

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intendent of insurance in the case of corporations organized and operating under article nine-c of the insurance law.

(b) Notwithstanding the foregoing provisions of paragraph (a) above, rates of payment for hospital and health-related service made by government agencies, approved by the state director of the budget and in effect March thirty-first, nineteen hundred sixty-nine shall continue in effect for the period ending December thirty-first, nineteen hundred sixty-nine. Rates approved by the state director of the budget for the first time after March thirty-first, nineteen hundred sixty-nine shall continue in effect for the period ending December thirty-first nineteen hundred sixty-nine.

(c) Notwithstanding any inconsistent provision of law, rates of payment for government agencies for general hospital out-patient and emergency services, and for treatment or diagnostic center services during the period January first, nineteen hundred seventy-six through March thirty-first, nineteen hundred seventy-seven shall be at no more than one hundred percent of the approved nineteen hundred seventy-five rates for such services.

(d) For the purpose of this subdivision approved nineteen hundred seventy-five rates shall mean those rates originally approved by the state director of the budget, together with any approved rate revisions. Nothing contained herein shall be deemed to preclude further revisions as the result of audits conducted pursuant to section twenty-eight hundred three of this chapter.

(e) During the period beginning January first, nineteen hundred seventy-six, and ending March thirty-first, nineteen hundred seventy-seven, the commissioner may determine and certify to the director of the budget rates of payment for residential health care facilities without regard to the provisions of subdivision three of this section. The commissioner is directed to formulate such rates in accordance with the provisions of paragraph c of subdivision one of section twenty-eight hundred three and section twenty-eight hundred eight of this chapter which rates shall be effective for the period hereinbefore specified in this paragraph notwithstanding any inconsistent provision of such section twenty-eight hundred eight.

¹ Insurance Law, § 250 et seq.

§ 12. Section twenty-eight hundred seven of such law is hereby amended by adding thereto two new subdivisions, to be subdivisions two-a and two-b, to read, respectively, as follows:

2-a. Prior to the approval of rates of payment for hospitals, exclusive of residential health care facilities and outpatient and emergency services and treatment and diagnostic centers, made by government agencies, the state director of the budget shall take into consideration economic conditions within the state which affect the economic resources available to meet the cost of government-funded medical services. If economic conditions are determined by such director to be likely to have a severe adverse effect on the ability of the state government to make sufficient resources available to purchase medical care at the proposed rates, the director shall return the proposed rates to the commissioner, and direct him to revise the rates to comply with the director's findings. Such revised rates shall not be certified to the

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superintendent of insurance for corporations organized and operating in accordance with article nine-C of the insurance law which corporations shall continue to be subject to the rates of payment otherwise established pursuant to law.

2-b. There shall be a hospital rate review board in the department consisting of the comptroller, the director of the budget, the commissioner of health who shall serve as chairman, one member appointed by the governor upon nomination by the temporary president of the senate, and one member appointed by the governor upon nomination by the speaker of the assembly. The members appointed by the governor upon the nomination of the temporary president of the senate and the speaker shall receive reimbursement for actual and necessary expenses. The board shall hear appeals from the rate determinations made pursuant to subdivision two-a of this section. The board shall uphold the decision of the director of the budget unless the appellant can establish that: the rate of payment allowed is inadequate to provide care equal to that required to meet minimum acceptable standards and procedures required by section twenty-eight hundred three of this article; and that the costs of providing such care are reasonably related to the efficient production of medical care and services. Whenever the board shall find that the rate of payment is insufficient to provide for the efficient production of medical care and services equal to that required to meet the minimum acceptable standards and procedures required by section twenty-eight hundred three, it shall direct the commissioner of health to certify a revised rate of payment sufficient to meet such standards.

§ 13. Section twenty-eight hundred seven of such law is hereby amended by adding thereto a new subdivision, to be subdivision four, to read as follows:

4. The commissioner shall notify each hospital and health-related service of its approved rate at least sixty days prior to the beginning of an established rate period for which the rate is to become effective.

§ 14. Section sixty-eight hundred sixteen of the education law is hereby amended by designating the text thereof as subdivision one, and by adding thereto a new subdivision, to be subdivision two, to read as follows:

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter. The written order of a physician for items not subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter shall be construed to be a direction, a fiscal order or a voucher.

§ 15. Subdivision (a) of section one hundred fifty-eight of the social services law, as amended by chapter one hundred ninety-eight of the laws of nineteen hundred seventy-five, is hereby amended to read as follows:

(a) Any person unable to provide for himself, or who is unable to secure support from a legally responsible relative, who is not receiving needed assistance or care under other provisions of this chapter, or from other sources, shall be eligible for home relief; provided, however that no person under the age of twenty-one years except a

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married person living with their spouse, living apart from a legally responsible relative shall be eligible for home relief unless a proceeding has been brought by or on behalf of such person to compel such legally responsible relative to provide for or contribute to such person's support and until an order of disposition has been entered in such proceeding. However, a person who shall be eligible for aid to dependent children according to the provisions of title ten of this article¹ shall be granted aid to dependent children and while receiving such aid shall not be eligible for home relief. A person who is receiving federal supplemental security income payments and/or additional state payments shall not be eligible for home relief. An applicant for home relief who reasonably appears to meet the criteria for eligibility for federal supplemental security income payments shall be required, as a condition of eligibility for home relief, to apply for such payments and shall, if otherwise eligible therefor, be eligible for home relief until he has received a federal supplemental security income payment. Such applicant shall also be required, as a condition of eligibility for home relief, to sign a written authorization allowing the secretary of the federal department of health, education and welfare to pay to the social services district his initial supplemental security income payment and allowing the social services district to deduct from his initial payment the amount of home relief granted for any month in which he had applied for and been found eligible for supplemental security income benefits.

¹ Social Services Law, § 343 et seq.

§ 16. The effectiveness of the provisions of subdivision four of section twenty-eight hundred seven of the public health law, as added by chapter six hundred eighty-two of the laws of nineteen hundred seventy-four, are hereby suspended and shall, for all purposes whatsoever, be deemed to have been without any force or effect from and after November first, nineteen hundred seventy-five.

§ 17. If any provision of this act, or the application thereof to any person or circumstance, be held unconstitutional, invalid or ineffective, in whole or in part, the remainder of this act, or the application of such provision to persons or circumstances other than those to which it was held unconstitutional, invalid or ineffective, shall not be affected thereby. If any exception to any limitation on the care, services or supplies that may be furnished as an item of medical assistance as provided for in this act be held unconstitutional, invalid or ineffective, the limitation shall remain in effect without any exception.

§ 18. This act shall take effect immediately; provided, however, that sections two and fourteen shall take effect on the thirtieth day next succeeding such effectiveness, sections three, four, five, six, seven, ten and fifteen shall take effect on the forty-fifth day next succeeding such effectiveness, sections eight, eleven and twelve shall be deemed to have been in full force and effect on and after the first day of January, nineteen hundred seventy-six. Provided, however, that the provisions of sections twelve, thirteen and sixteen of this act shall be and remain effective only to and including March thirty-first, nineteen hundred seventy-seven and shall be thereafter effective only in respect to any act done on or before such date or action or proceeding arising out of such act. The state commissioners of health, social services and education shall, prior to such effective dates, take all necessary steps to inform providers and recipients of medical assistance of the provisions of this act and are authorized to take such other steps as may be necessary to effectuate the purposes of this act. This act shall apply to care, services and supplies furnished on and after the applicable ef-

fective date. This act shall not be construed to alter, change, affect, impair or defeat any rights, obligations, duties or interests accrued, incurred or conferred prior to the enactment of this act, nor shall this act be interpreted so as to deny care, services or supplies to any individual if such care, services and supplies are necessary in order to complete a course of treatment initiated prior to the enactment of this act.

Education—Licenses, Permits, Etc.—Fees, Appropriations

CHAPTER 77

An Act to amend the education law, in relation to fees for professional examinations, limited permits, licenses and miscellaneous registration fees, and making an appropriation therefor.

Approved March 30, 1976, effective April 1, 1976.

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Section one hundred ten of the education law is hereby amended to read as follows:

§ 110. Refunds

1. Moneys received by the state education department pursuant to this chapter prior to July first, nineteen hundred forty-two, may be refunded: (a) Where such moneys were not required by law or regents' rule. (b) Where such moneys were in excess of the amounts required by law or regents' rule. (c) Where fees are paid by applicants who are not permitted to enter examinations for which such fees are paid. Any such moneys received after July first, nineteen hundred forty-two shall not be so refunded unless application for such refund has been made within two years after its receipt by the state education department.

2. Applicants for professional licenses not receiving such licenses may be granted partial refunds not exceeding fifty percent of the fee paid to the department unless they have failed the examinations for such licenses, in which case such applicants may not receive a refund. Each applicant for a professional license who has at any time received a partial refund of an initial license application fee shall pay all required fees upon submitting any subsequent application for initial licensure.

§ 2. Section two hundred twelve of such law, as amended by chapter six hundred ninety-one of the laws of nineteen hundred fifty-seven, is hereby amended to read as follows:

§ 212. Fees

The department shall charge the following fees:

1. For the issuance of a qualifying certificate for admission to a professional school as required by or pursuant to law, five dollars.

2. For admission to a special examination in English authorized or required by or pursuant to law as a pre-requisite to admission to a professional school or to an examination for a license to engage in or practice a profession, ten dollars.

3. For replacement licenses, duplicate registration certificates, detailed certifications of licensure records and other certifications or permits for which fees are not otherwise provided, fees as fixed by regulations of the department.

~~deletions by strikeouts~~

65

Exhibit B

I HEREBY CERTIFY that the attached amendments to Part 85, Subchapter K, Chapter II, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are promulgated this 17th day of May, 1976, to be effective upon filing with the Secretary of State, pursuant to the authority vested in the Commissioner of Health by Chapter 76 of the Laws of 1976.

Sections 85.10 through 85.14 were adopted and filed on April 29, 1976 as an emergency measure pursuant to the authority contained in Executive Law § 101-a(3), and the aforesaid sections would, pursuant to the same law, expire sixty days after date. Pursuant to the aforesaid statute I hereby take final action with regard to §§ 85.10 through 85.14, and I hereby make said sections permanent.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the seal of the New York State Department of Health to be affixed this 17th day of May, 1976.


ROBERT P. WHALEN, M.D.
Commissioner of Health

bcc: Temporary President, Senate
Legislative Counsel to the Speaker

Pursuant to the authority vested in the Commissioner of Health by Chapter 76 of the Laws of 1976, I hereby add Part 85 of Subchapter K of the Administrative Rules and Regulations contained in Chapter II, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, this ~~14th~~ day of May 1976, to be effective upon filing with the Secretary of State, as follows:

17th

PART 85

MEDICAL ASSISTANCE BENEFITS

SURGERY

- Sec.
85.1 Emergency or urgent surgery
85.2 Standards for surgical
intervention
85.3 Deferrable surgery
85.4 One-day presurgical stay
limitation

LIMITATION ON HOSPITAL STAY

- 85.5 Limitation on hospital stay

PHYSICALLY HANDICAPPED CHILDREN

- Sec.
85.6 Physically handicapped children

NON-PRESCRIPTION DRUGS IN THE MEDICAID PROGRAM

- 85.10 Definitions
85.11 Establishment of list of
reimbursable, non-prescription
drugs
85.12 Maximum reimbursable price
schedule for non-prescription
drugs
85.13 Limitations
85.14 Revisions to list and price
schedule of non-prescription
drugs

PART 85
Medical Assistance Benefits
SURGERY

Section 85.1 Emergency or urgent surgery.

- (a) To be a covered benefit under medical assistance for the needy as provided in section 365-a(5)(a) of the Social Services Law, any emergency or urgent surgery shall be for alleviation of severe pain or for the immediate diagnosis and/or treatment of conditions which threaten disability or death if not promptly diagnosed or treated. No such emergency or urgent surgery requires prior determination of coverability. In each case, a person designated by the Commissioner of Health shall determine coverability of this benefit based upon the documented existence of one or more conditions such as the following:
- (1) obstetrical crises and/or labor.
 - (2) acute trauma.
 - (3) reparative or reconstructive surgical procedures performed within sixty days of acute trauma.
 - (4) malignancy, confirmed or suspected.
 - (5) hemorrhage or threat of hemorrhage.
 - (6) serious infection.
 - (7) severe pain.
 - (8) shock or impending shock.
 - (9) decompensated vital functions or threat to vital functions such as sensorium, respiration, circulation, excretion and sensory organs.
 - (10) congenital defects or abnormalities in a newborn infant best managed by prompt intervention.
 - (11) any condition the management of which requires prompt diagnostic procedures necessarily performed on an inpatient basis such as biopsy and endoscopy.
 - (12) any other condition which causes severe pain or threatens disability or death if not promptly diagnosed or treated.
- (b) Determination of benefit coverability under this section may be made by a designated physician or non-physician under a designated physician's supervision as provided in subdivision (a) of this section. A determination of non-coverability shall be made only by a designated physician. If such determination of non-coverability is made, any care, supplies or services provided shall not be a covered benefit under medical assistance for the needy.

- (c) Notice of determination of coverability shall be given to the patient's surgeon, the hospital administrator and if there is a determination of non-coverability to the patient. The hospital shall keep any such notification on file, accessible for review by representatives of the State or of the local social services district. The patient's surgeon may, within thirty days of the date of such notification, appeal such determination of non-coverability in writing to a physician or physicians designated by the commissioner for such purpose. Notification of the decision on appeal shall be given to the patient's surgeon, the hospital administrator and the patient. If determination of non-coverability is affirmed on appeal, the period for which approval was requested shall not be a covered benefit.
- (d) Any hospital care, services or supplies covered as a benefit under this section shall be subject to length of stay limitations of section 365-a(2)(b) of the Social Services Law and section 85.5 of this Part.

85.2 Standards for surgical intervention.

- (a) To be covered benefit under medical assistance for the needy as provided in section 365-a(5)(b) of the Social Services Law specified surgical procedures shall meet the standards for intervention established in this section. In each case a person designated by the Commissioner of Health shall determine coverability of this benefit prior to admission in response to a written request from the responsible surgeon. The specified procedures are:
- (1) cataract surgery to restore vision.
 - (2) eye muscle surgery to correct strabismus and to prevent functional loss when binocular vision still exists.
 - (3) myringotomy, with or without tube insertion to preserve hearing.
 - (4) tubal ligation or vasectomy to interdict conception.
 - (5) termination of pregnancy.
- (b) The patient's surgeon shall ensure that the applicable standards for any of the specific procedures specified in subdivision (a) of this section are met and documented within the hospital medical record of the patient. Such medical record shall be accessible to the commissioner, or his designee, for review.
- (c) A determination of benefit coverability under this section shall be made by a designated physician or non-physician under a designated physician's supervision. A determination of non-coverability shall be made only by a designated physician. If such non-coverability determination is made, any care, supplies or services provided shall not be a covered benefit under medical assistance for the needy.
- (d) Notice of determination shall be given to the patient's surgeon, the hospital administrator and if there is determination of non-coverability to the patient. The hospital shall keep any such notification on file, accessible for review by representatives of the State or of the local social services district. The patient's surgeon may within 30 days of such notification, appeal a determination of non-coverability to a physician or physicians designated by the commissioner for such purpose. Notification of decision on appeal shall be given to the patient's surgeon, the hospital administrator and the patient. If the determination of non-coverability is affirmed on appeal, any care, supplies or services provided for such purpose shall not be a covered benefit.
- (e) Any hospital care, services or supplies covered by this section shall be subject to the length of stay limitations of section 365-a(2)(b) of the Social Services Law and section 85.5 of this Part.

85.2

85.3 Deferrable surgery.

- (a) To be a covered benefit under medical assistance for the needy as provided in section 365-a(5)(c) of the Social Services Law, any surgery not coverable as emergency or urgent surgery under section 365-a(5)(a) or which does not meet standards for surgical intervention under section 365-a(5)(b) shall require a determination of coverability by a person designated by the Commissioner of Health prior to admission. A determination of coverability shall be based on the likelihood that deferral of the proposed surgery for six months or more may jeopardize life or essential function, or cause severe pain.
- (b) The required determination of coverability shall be initiated by written request from the proposing surgeon, with information adequate for making the determination. A determination of coverability shall be made by a designated physician or non-physician under supervision of a designated physician. A determination of non-coverability shall be made only by a physician.
- (c) Prior to making a determination, the designated person may require a written second opinion from a qualified specialist designated by the Commissioner of Health. A written second opinion shall be based upon an examination of the patient and a review of information about the patient provided by the proposing surgeon. A second written opinion under this section shall in every instance be required for the following surgical procedures except when performed as urgent or emergency surgery as set forth in this Part, or when not required under the provisions of the physically handicapped children's program:
- (1) tonsillectomy and/or adenoidectomy ..
 - (2) herniorrhapy.
 - (3) hemorrhoidectomy..
 - (4) hysterectomy.
 - (5) cholecystectomy .
 - (6) spinal fusion or laminectomy.
 - (7) joint cartilage surgery.
- (d) If, in any area, reasonable patient access to specialists designated to give second opinions is lacking, the Commissioner of Health may provide for other mechanisms to assist his designee in making determination of coverability.
- (e) A written second opinion may be required by the department for any deferrable surgery to be performed within specific hospitals or by specific surgeons when review reveals unusual, aberrant or questionable practices, or practices not in conformity with provisions of this section.

85 3

- (f) Notice of determination shall be given to the proposing surgeon who shall, if coverability is determined, incorporate such notice in the hospital record at admission.
- (g) The proposing surgeon may appeal any determination of non-coverability to a physician or physicians designated by the Commissioner of Health for such purpose. Notification of decision on appeal shall be given to the proposing surgeon who shall incorporate any notice of determination of coverability in the hospital record at admission.
- (h) Any hospital care, services or supplies as a benefit covered under this section shall be subject to length of stay limitations of section 365-a(2)(b) of the Social Services Law and section 85.5 of this Part.

85.4 One-Day presurgical stay limitation.

- (a) To be a covered benefit under medical assistance for the needy, provided in section 365-a(5)(d) of the Social Services Law, any presurgical hospital stay of more than one day for surgical benefits covered by sections 365-a(5)(b) and 365-a(5)(c) shall require a determination of coverability prior to admission by a person designated by the Commissioner of Health. Such determination of coverability shall be for a specified maximum period of presurgical stay. A written request for such determination shall be made by the patient's surgeon, proposing the total length of presurgical stay, and citing conditions requiring such exceptional stay. A determination of coverability shall be based upon existence of conditions which require inpatient preparation of more than one day to improve operative risk status such as:
- (1) correction of significant fluid or electrolyte imbalance.
 - (2) transfusion to correct significant anemia.
 - (3) stabilization of congestive heart failure.
 - (4) improvement of pulmonary function or drainage.
 - (5) hyperalimentation to correct significant malnutrition.
 - (6) gastro-intestinal preparation before gastrointestinal surgery.
 - (7) stabilization of significant endocrine disorder.
 - (8) hematologic and immunologic preparation for organ transplant.
 - (9) management of infection.
 - (10) essential preliminary studies and procedures performable only on an inpatient basis.
- (b) Determination of coverability shall be made by a designated physician or non-physician under physician supervision. A determination of non-coverability shall be made only by a designated physician. Notice of determination shall be given to the patient's physician who shall, in case of extended coverability, incorporate such notice in the patient's medical record at admission. No presurgical stay of more than one day will be a covered benefit without such prior determination of coverability and its incorporation in the patient's medical record.
- (c) The patient's physician may appeal any determination of non-coverability to a physician or physicians designated by the commissioner for such purpose. Notification of decision on appeal shall be given to the patient's physician, who shall incorporate such notification in the patient's medical record at admission.

85.5 Limitation on hospital stay

- (a) To be a covered benefit under medical assistance for the needy as provided in section 365-a(2)(b) of the Social Services Law, any hospital stay beyond twenty days per spell of illness during which all or any part of the cost of such care, services and supplies are claimed as items of medical assistance shall require a prior determination of coverability by a person designated by the Commissioner of Health. Any hospital stay for physical medicine and related rehabilitation care, pursuant to an established rehabilitation plan in a rehabilitation hospital or rehabilitation unit, beyond forty days shall also require such prior determination of coverability. A written request for such determination shall be made by the patient's physician. Such request shall include evidence documented in the patient's medical record showing that in order to preserve life or to prevent substantial risk of continuing disability, an additional period of care is required of such complexity or intensity that it can be provided only in a hospital. Care of such complexity or intensity shall include, but not be limited to:
- (1) severe burns requiring continued therapy in a burns unit.
 - (2) continuing cardiovascular, renal or pulmonary decompensation requiring care in a coronary care unit, intensive care unit, pulmonary care unit or other acute care setting in the hospital.
 - (3) central nervous system damage with threatened or impaired consciousness.
 - (4) persistent fever or serious infection.
 - (5) persistent hemorrhage or threat of recurrent hemorrhage.
 - (6) life threatening conditions including malignancy when chemotherapy, radiotherapy or other therapy can be provided and monitored effectively only in a hospital.
 - (7) conditions requiring physical rehabilitation under an established rehabilitation plan when such treatment can be carried out only in a hospital setting.
- (b) Such request for determination of coverability for continued care shall be made before the twentieth but not before the sixteenth day of stay. The determination of coverability shall be for an additional period not to exceed 10 days after the twentieth day of stay. Determination of coverability shall be made for additional periods of stay not to exceed 10 days each pursuant to written requests submitted as aforesaid prior to expiration of the last period for which there has been a determination of coverability.

- (c) In the case of physical medicine and related rehabilitation care referred to in subdivision (a) of this section, the request for extended coverability determination shall be made before the fortieth but not before the thirty-sixth day of stay, and determination of coverability shall not exceed 20 days for the initial additional period of stay and for any additional period thereafter.
- (d) Spell of illness, for the purpose of this section, shall begin on the first day of hospital care and shall end 60 days following discharge from the hospital inpatient service. Except in case of emergency or urgency, readmission during said 60 day period shall be subject to the prior approval of the commissioner's designee upon a showing of necessity to preserve life or to prevent substantial risk of disability.
- (e) A determination of coverability may be granted by a designated physician or non-physician under the supervision of a physician. A determination of non-coverability shall be made only by a designated physician. Notice of determination shall be given to the patient's physician, the hospital administrator, and if there is a determination of non-coverability to the patient. A written record of determinations made of such coverability or non-coverability shall be entered in the hospital records and made available for review.
- (f) The patient's physician may, within three days of a determination of non-coverability of continued care, appeal such determination to the physician or physicians designated by the Commissioner of Health for such purpose. Notice of decision on appeal shall be given to the patient's physician, the hospital administrator and patient. If there is a determination of non-coverability or such determination of non-coverability is affirmed on appeal, any care, services or supplies provided for such purpose during the additional period of stay requested shall not be a covered benefit.

PHYSICALLY HANDICAPPED CHILDREN

85.6 Physically handicapped children.

For persons under the age of 21 years having conditions covered under the scope of the physically handicapped children's program, all determinations of coverability in this Part shall be made by the physically handicapped children's program county medical director, the county commissioner of health or the health services administration of the City of New York as the designee of the Commissioner of Health. Such designee may utilize any diagnosis and evaluation carried out in a center approved by the physically handicapped children's program as the second opinion upon which determination of coverability is made, or may require an additional second opinion.

NON-PRESCRIPTION DRUGS IN THE MEDICAID PROGRAM

85.10 Definitions. As used in the sections under the heading "Non-Prescription Drugs in the Medicaid Program" (§ 85.10 et seq. of this Part), unless the context otherwise requires:

(a) Non-prescription drug means a drug, commonly referred to as a non-legend or over the counter drug, which may be sold at retail by a pharmacy to the general public. Neither Federal law nor regulations of the commissioner require that such drugs be distributed or dispensed on prescription. The provisions of Education Law, section 6810(1) and the first unnumbered paragraph of Section 6816 are not applicable to the sale, distribution or dispensing of such non-prescription drugs.

(b) Medical assistance program means the New York State medical assistance to the needy program (Medicaid) authorized by article 5 of title 11 of Social Services Law.

(c) Commissioner means Commissioner of Health of the State of New York.

(d) Package size. For purposes of this Part, package size on non-prescription drug means the amount of medication required to fill a request or order for such drug. Under the medical assistance program, reimbursement for non-prescription drugs shall not be greater than the price for the available manufacturers' package or unit size which most closely corresponds to the quantity requested on such written request or order.

85.11 Establishment of list of reimbursable, non-prescription drugs. Pursuant to Section 365-a of the Social Services Law non-prescription drugs listed in the therapeutic categories listed below may be reimbursed in the New York State medical assistance program:

(a) Analgesic and Antipyretic:

<u>Product</u>	<u>Quantity</u>	<u>§ 85.12(b) Price</u>
(1) Acetaminophen	120 mgm. tablets 24's	\$1.35
Acetaminophen	325 mgm. tablets 24's	0.72
	100's	1.85
	225's	4.15

I	Acetaminophen	Elixir 2 oz.	\$ 1.19
		4 oz.	2.09
	Acetaminophen	Drops 15cc	1.39
	Acetaminophen	Syrup 4 oz.	1.88
T	Acetaminophen	125 mgm. suppositories	
		12's	2.75
		300 mgm. suppositories	
		12's	2.85
		600 mgm. suppositories	
		12's	3.00
A	(2) Acetylsalicylic Acid		
		1 1/4 Grain tablets 36's	0.49
L	Acetylsalicylic Acid		
		5 Grain tablets 50's	0.94
		100's	1.25
		250's	1.80
I	Acetylsalicylic Acid		
		5 Grain capsules 100's	1.95
C	Acetylsalicylic Acid		
		5 Grain tablet enteric	
		Coated 100's	1.95
		250's	2.39
	Acetylsalicylic Acid		
S		5 Grain suppositories	
		6's	2.19
		10 Grain suppositories	
		6's	2.39

I	(b) <u>Antacid.</u>		\$85.12(b)
	<u>Product</u>	<u>Quantity</u>	<u>Price</u>
	(1) Aluminum Hydroxide suspension		
		12 oz.	\$ 1.99
		26 oz.	3.79
T	Aluminum Hydroxide tablets		
		100's	2.29
	(2) Aluminum Hydroxide with Magnesium Hydroxide or Magnesium Trisilicate and/or Simethecone		
		Suspension 12 oz.	2.19
		26 oz.	3.79
A		Tablets 50's	1.20
		100's	2.29
	(3) Milk of Magnesia (See laxatives.)		
	(c) <u>Antiasthma.</u>		\$85.12(b)
	<u>Product</u>	<u>Quantity</u>	<u>Price</u>
L	Ephedrine, Theophylline and Phenobarbital combina- tions		
		Tablets 100's	\$7.13
		Suspension 8 oz.	3.89
		16 oz.	7.27
I	(d) <u>Antivertigo.</u>		\$85.12(b)
	<u>Product</u>	<u>Quantity</u>	<u>Price</u>
	Dimenhydrinate	50 mgm. 12's	1.09
	(e) <u>Cough and cold.</u>		\$85.12(b)
	<u>Product</u>	<u>Quantity</u>	<u>Price</u>
	(1) 1/4% Phenylephrine Hydrochloride nasal solution		
C		30cc	1.29
	1/2% Phenylephrine Hydrochloride nasal solution		
S		30cc	1.49
	(2) Glyceryl Guaiacolate syrup		
		4 oz.	1.50
		8 oz.	2.39

I

(3) Non-narcotic antitussants and antihistamine syrup

4 oz.	\$ 1.98
8 oz.	3.60

(4) Diphenhydramine syrup

4 oz.	2.36
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T

(f) Dermatological.

\$ 85.12(b)

<u>Product</u>	<u>Quantity</u>	<u>Price</u>
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(1) Bacitracin ointment

1/2 oz.	1.49
1 oz.	1.98

(2) Neomycin ointment

1/2 oz.	1.49
1 oz.	1.98

A

(3) Tolnaftate

Cream 1% 15 gm.	3.80
Powder 1% 45 gm.	1.98

(g) Family planning.

L

<u>Product</u>	<u>Quantity</u>	<u>Price</u>
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\$ 85.12(b)

(1) Contraceptive cream

Small	2.75
Large	3.75
Kit, with applicator	3.50

I

(2) Contraceptive jelly

C

Small	2.75
Large	3.75
Kit, with applicator	3.50

S

(3) Contraceptive suppositories

12's	1.98
------	------

(4) Contraceptive foam

20 gm.	3.25
50 gm.	4.95
6's disposable applicator	2.98
10's disposable applicator	4.50

I

(h) Fecal softener and laxative.\$ 85.12(b)
Price(1) Product Quantity
Milk of Magnesia suspension

12 oz.	\$1.27
16 oz.	1.40
26 oz.	1.95
32 oz.	1.99

T

Milk of Magnesia tablets

30's	0.49
100's	1.35
200's	2.19

A

(2) Heavy mineral oil

8 oz.	1.20
16 oz.	2.00
32 oz.	2.75

L

(3) 5 Grain Cascara Sagrada tablets

100's	2.10
-------	------

5 Grain Cascara Sagrada fluid extract

4 oz.	1.39
-------	------

I

(4) 50 mgm. Dioctyl Sodium Sulfosuccinate
capsules

30's	3.23
------	------

C

50 mgm. Dioctyl Sodium Sulfosuccinate capsules

60's	5.78
------	------

S

100 mgm. Dioctyl Sodium Sulfosuccinate capsules

30's	3.87
------	------

100 mgm. Dioctyl Sodium Sulfosuccinate capsules

60's	7.05
------	------

(5) 10 mgm. Bisacodyl suppositories

4's

\$1.79

(i) Hematinic.

\$ 85.12(b)
Price

T

Product Quantity
5 Grain Ferrous Sulfate tablets

100's

1.89

5 Grain Ferrous Sulfate tablets, enteric coated

100's

1.89

A

Ferrous Sulfate syrup

16 oz.

4.00

Ferrous Sulfate drops

15 cc

1.35

L

Ferrous Sulfate drops

50 cc

2.79

I

5 Grain Ferrous Gluconate tablets

100's

1.98

(j) Insulin.

C

Product

\$ 85.12(b)
Price
Regular

\$ 85.12(b)
Price
Pork

\$85.12
Price
Beef

(1) 40 Units Insulin
regular

S

10cc

\$1.90

\$3.30

\$2.20

80 Units Insulin
regular

10cc

3.59

6.23

4.17

100 Units Insulin
regular

10 cc

4.49

7.78

5.19

82

- 15 -

2
(2) 40 Units Insulin globin

10 cc 2.27 - -

80 Units Insulin globin 4.30 - -

100 Units Insulin globin 5.37 - -

T

(3) 40 Units Insulin Pro-
tamine Zinc

10 cc 2.25 - 2.58

80 Units Insulin Pro-
tamine Zinc

10 cc 4.09 7.12 4.72

100 Units Insulin Pro-
tamine Zinc

10 cc 5.15 - -

(4) 40 Units Insulin NPH

10 cc 2.25 3.95 2.58

80 Units Insulin NPH

10 cc 4.09 7.12 4.72

100 Units Insulin NPH

10 cc 5.15 8.88 5.90

(5) 40 Units Insulin Lente
(all)

10 cc 2.25 3.95 2.58

80 Units Insulin Lente
(all)

10 cc 4.09 7.12 4.72

100 Units Insulin Lente
(all)

10 cc 5.15 8.88 5.90

I

(k) Vitamin/Mineral

<u>Product</u>		<u>Quantity</u>	<u>\$ 60.4(b) Price</u>
(1)	ACD Solution	50cc	\$ 3.44
	ACD Solution with iron	50cc	3.44
(2)	Multi-vitamin solution	30cc	2.85
	Multi-vitamin solution	50cc	4.15
	Multi-vitamin solution with iron	50cc	4.15
(3)	Multi-vitamin capsules or tablets	100's	3.60
	Multi-vitamin with minerals	100's	3.60
(4)	Therapeutic vitamins and minerals or tablets	30's	2.50
		100's	7.50
(5)	Prenatal vitamins capsules or tablets	100's	4.98
(6)	Ascorbic acid	100 mgm. 100's	1.79
		250 mgm. 100's	3.49
		500 mgm. 100's	5.95
(7)	Calcium	7 1/2 gr. 100's	1.19
		10 gr. 100's	1.49

85.12 Maximum reimbursable price schedule for non-prescription drugs. Pursuant to section 365-a of the Social Services Law the price schedule for those non-prescription drugs specified in this Part by the Commissioner as a reimbursable item of medical assistance shall be the lowest of:

- (a) the provider's usual and customary price to the general public on date of provision of service; or
- (b) the maximum reimbursable stipulated price established by the Commissioner based on the package size of drugs most frequently purchased by providers and approved by the Director of the Budget for each package size of non-prescription drug as listed in Section 85.11 of this Part.

I

85.13 Limitations.

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(a) The maximum reimbursable price that may be paid to a provider for those non-prescription drugs allowed for payment in the medical assistance program shall not exceed the lowest sale price to the general public for the particular drug on the date of provision of such drug.

(b) Under no circumstances shall a dispensing fee or a fixed percent of mark-up be paid for providing non-prescription drugs.

85.14 Revisions to list and price schedule of non-prescription drugs. Changes and/or revisions in the list of allowable non-prescription drugs and price schedule for such drugs shall be made in accordance with the following:

(a) the list of reimbursable non-prescription drugs shall be amended, as deemed necessary by the commissioner;

(b) a completely revised maximum reimbursable price schedule shall be established at a minimum of every six months.

L

I

C

S

A P P R O V E D:

s/ Howard F. Miller
for the Director of the Budget

Dated: April 29, 1976

86

Exhibit C

STATE OF NEW YORK
DEPARTMENT OF SOCIAL SERVICES
1450 WESTERN AVENUE
ALBANY, NEW YORK 12243

DRAFT ONE

ADMINISTRATIVE LETTER

TRANSMITTAL NO.:

TO: Commissioners of Social Services

DATE:

SUBJECT: Institutional Services Utilization Review Program:
Instructions for Payment of Medical Assistance Inpatient
Claims

SUGGESTED
DISTRIBUTION: Medical Assistance Staff
Accounting Staff

PURPOSE:

The purpose of this release is to provide instruction for the payment of Medical Assistance Claims associated with an adverse decision rendered by a Professional Standard Review Organization (PSRO) or a facility Utilization Review (UR) Committee.

CONTACT PERSON:

Any questions regarding this release should be directed to _____ by calling 800/342-3710, extension 7_____.

BACKGROUND:

Utilization Review is a program whereby medical and other health care professionals oversee, on a concurrent and retrospective basis, the quality, necessity and appropriateness of inpatient health care services.

FILING REFERENCES

Previous ADMs INFs	Dept. Regs.	Social Services Law and Other Legal References	Bulletin/Chapter Reference	Miscellaneous References
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DRAFT ONLY

There are two mechanisms which may be used to review institutional care and services; the facility UR Committee or the Professional Standards Review Organization (PSRO). The facility UR Committee functions in accordance with a Utilization Review Plan prepared by the facility pursuant to Federal regulation. The PSRO functions in accordance with their Formal Plan which has been approved by the Department of Health, Education, and Welfare. The facility UR committee operates within a given facility; the PSRO within a given area (attachment 1 indicates PSRO areas in New York State). The facility UR committee actually conducts the review of care and services within the facility; the PSRO may either directly review the care and services provided within a facility or delegate such review to the facility. At the current time, the PSROs operating in Conditional Status within New York State (attachment 2) are only reviewing hospital services for Medicare patients (attachment 3, Delegated and Non-delegated Hospitals). Review of Medicaid patients will commence August 1, 1976 for PSRO's currently in operation.

PSRO/FACILITY UR COMMITTEE NOTIFICATION TO SOCIAL SERVICES DISTRICTS

A. Hospitals:

Local social services districts will be notified of all PSRO or facility UR Committee determinations regarding the necessity and appropriateness of an individual's admission to or continued stay in the hospital via the PSRO/Facility Utilization Review Section of either the DSS-2140, Report on Inpatient Hospital Care, or W-220B, Hospital Care Authorization and Claim (attachment 4). This new section contains three items; (1) the date through which the PSRO or facility UR Committee has determined that hospital level

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facility UR Committee made an adverse determination regarding the necessity and appropriateness of hospital care and (3) the denial of the necessity for admission. Only one item will be checked by the UR Committee or PSRO on each bill.

B. Skilled Nursing and Health Related Facilities:

Local social services districts will be notified only of adverse decisions regarding the necessity and appropriateness of continued stay in long term care facilities. Notification of the adverse decision shall be attached to the claim and shall contain the information indicated in (attachment 5).

Payment Limitations for Bills Associated with Adverse Decisions:

A. Hospital Bills:

1. Admission Review:

In cases where a PSRO or facility UR Committee determines that an individual's admission to a hospital was not necessary or appropriate, payment for care and services associated with such an unnecessary or inappropriate admission shall be limited to a maximum of three days from the admission date plus one additional day or to the date of discharge, whichever is earlier.

2. Continued Stay Review:

In cases where a PSRO or facility UR Committee determines that an individual's continued stay in the hospital is no longer necessary or appropriate, payment shall be made for care and services provided up to and including the effective date of the stay denial, as shown on the DSS-2140 or W-2203,

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NOTE:

If, in any case, the designee of the Commissioner of Health pursuant to the cost containment legislation (Chapter 76 of the Laws of 1976) has made a negative determination regarding the coverability of Medical Assistance benefits, payment shall be limited in accordance with such a negative determination. Any negative determination regarding the coverability of Medical Assistance benefits rendered by the Commissioner of Health's designee shall supercede any positive determination on the necessity and appropriateness of care rendered by a PSRO or facility UR Committee.

B. Skilled Nursing and Health Related Facility Bills:

1. Admission Review:

A review of the necessity and appropriateness of an individual's admission to a skilled nursing or health related facility is not required by Utilization Review regulations.

2. Continued Stay Review:

In those cases where a facility UR Committee has determined that an individual's continued stay in a long term care facility is no longer necessary or appropriate, payment shall be made for care and services provided up to and including the final determination date of the continued stay review plus one additional day, or the date of discharge, whichever is earlier.

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Extension of Payment Following an Adverse Decision for Patient's
Awaiting Placement in Alternate Levels of Care:

A. Hospital Patients:

If a patient continues to require hospitalization pending placement to an alternate level of care, payment shall continue in accordance with 74-ADM-25 (Hospital Inpatient Utilization Review Program) and 76-ADM-52 (Maximum Utilization of Medicare: Availability of Medicare for Hospitalized Patients Who Are Awaiting SNF Placement). Additionally, the hospital must complete the Alternate Care Section of the DSS-2140 or W-220B. Payment shall not be continued beyond that outlined in Paragraphs A (1) and (2) above for hospital patients adjudged ready for discharge to the community.

NOTE:

To be a covered benefit under Medical Assistance, such continuation of care must be approved by the designee of the Commissioner of Health.

B. Skilled Nursing and Health Related Facility Patients:

If a patient continues to require skilled nursing or health related facility placement pending placement to an alternate level of care, payment shall continue so long as the facility notifies the local district of the individual's need for an alternate level of care and documents the effort made to secure an appropriate placement for the individual. Payment shall not be continued beyond that outlined in Paragraph (B) (2) (above) for skilled nursing or health related facility patients adjudged

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Notification to Recipients of Their Right to Appeal an Adverse Decision:

A. PSRO Appeals Process:

1. An appeal to a PSRO is applicable only for adverse decisions made by a PSRO or PSRO delegated U.R. Committee.
2. Any review or appeals provided by PSROs shall be in lieu of any fair hearing with respect to the same issue.
3. The recipient, practitioner and/or provider shall be notified of the right to a PSRO reconsideration hearing through the adverse decision notification form presented by the PSRO or the U.R. Committee delegated by the PSRO.
4. In cases where the PSRO reaffirms the negative determination in a reconsideration hearing and the matter in controversy is \$100 or more, the recipient, practitioner and/or provider has the right to a review of the determination by the State-wide PSRO Council.
5. In cases where the determination of the Statewide Professional Standards Review Council is adverse to the recipient, practitioner, or provider, they shall be entitled to a hearing by the Secretary of Health, Education, and Welfare and where the amount in controversy is \$1,000 or more, to a judicial review of the Secretary's final decision.
6. If during the course of the PSRO's appeal process, the adverse decision is overturned, the PSRO shall notify the local social services district.

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B. Fair Hearing:

1. Recipients wishing to appeal an adverse decision rendered by a facility UR committee have the right to request a fair hearing.
2. The recipient shall be given adequate notice of the determination by the facility UR committee.
3. The recipient shall not be entitled to a continuation of Medical Assistance payments, for a level of care adjudged inappropriate by a facility UR Committee, pending a fair hearing decision.

Seventeen PSRO areas are designated in New York, composed of the following counties:

Area I	
Niagara	Wyoming
Orleans	Chautauqua
Erie	Cattaraugus
Genesee	Allegany
Area II	
Monroe	Seneca
Wayne	Yates
Livingston	Steuben
Ontario	
Area III	
St. Lawrence	Cortland
Jefferson	Tioga
Oswego	Broome
Cayuga	Chemung
Onondaga	Schuyler
Tompkins	
Area IV	
Oneida	Lewis
Herkimer	Chenango
Madison	
Area V	
Franklin	Fulton
Clinton	Warren
Hamilton	Saratoga
Essex	Washington
Area VI	
Schenectady	Schoharie
Montgomery	
Area VII	
Otsego	Rensselaer
Albany	Delaware
Area VIII	
Greene	Ulster
Columbia	Dutchess
Sullivan	Orange
Area IX	
Putnam	Westchester
Area X	
Rockland	
Area XI	
New York	
Area XII	
Richmond	
Area XIII	
Kings	
Area XIV	
Queens	

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Nassau

Area XV

Bronx

Area XVI

Suffolk

Area XVIII

Attachment 2

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PSRO's which have signed Memorandum of Understanding with New York State:

Area

Name of Organization

I

Erie Region PSRO, Inc.

II

Genesee Region, PSRO, Inc.

V

Adirondack PSRO, Inc.

IX

Area 9 PSRO of New York State

X

PSRO of Rockland, Inc.

XI

New York County Health Services
Review Organization, Inc.

XIII

Kings County Health Care Review

XV

Nassau Physicians Review Organi-
zation, Inc.

XVI

The Bronx PSRO, Inc.

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Hospitals which have been formally designated delegated or non-delegated PSRO status:

Area I

<u>Hospital</u>	<u>Status</u>	<u>Effective</u>
Emergency Hospital	Delegated	6/14/76
Our Lady of Victory	Delegated	5/24/76
Sheridan Park	Non-Delegated	5/3/76
St. Francis	Delegated	6/1/76

Area II

Genesee	Delegated	9/2/75
Geneva General	Delegated	9/2/75
Highland	Delegated	4/12/76
Ira Davenport	Delegated	9/2/75
Lakeside Memorial	Delegated	1/26/76
Rochester General	Delegated	9/2/75
St. James Mercy	Delegated	1/26/76
St. Mary's	Delegated	9/2/75
Strong Memorial	Delegated	1/26/76
Nicholas H. Noyes Memorial Hosp.	Delegated	4/12/76

Area V

Emma Laing Stevens	Delegated	3/29/76
Mary McClellan	Delegated	3/29/76
Saratoga Hospital	Delegated	4/12/76

Area IX

Mental Retardation Inst. Flower and Fifth	Delegated	2/1/76
New Rochelle	Delegated	1/1/76
Peekskill	Delegated	4/19/76
St. Agnes	Delegated	4/19/76
St. Joseph's	Delegated	3/15/76
United Hospital	Delegated	3/15/76
White Plains Hospital Association	Delegated	2/1/76
Yonkers General	Delegated	2/1/76

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Area X

<u>Hospital</u>	<u>Status</u>	<u>Effective</u>
Ramapo General	Delegated	2/9/76
Nyack	Delegated	2/9/76

Area XI

Beekman - Downtown	Delegated	5/1/76
Lenox Hill	Delegated	3/15/76
Mount Sinai	Delegated	3/15/76
Regent Hospital	Non-Delegated	3/29/76
St. Vincent's	Delegated	5/1/76
Wadsworth	Non-Delegated	3/29/76

Area XIII

Lefferts General	Delegated	4/1/76
Long Island College Hosp.	Delegated	2/18/76

Area XV

Central General	Delegated	1/5/76
Community Hospital at Glen Cove	Delegated	11/28/75
Doctors Hospital (Lydia E. Hall Hosp.)	Delegated	11/28/75
Franklin General	Delegated	2/2/76
Hempstead General	Delegated	1/5/76
Long Beach Memorial	Delegated	2/2/76
Manhasset Medical Center	Delegated	2/2/76
Massapequa General	Delegated	2/2/76
Mercy Hospital	Delegated	9/30/75
Mid-Island	Delegated	9/30/75
Nassau County Medical Center, East Meadow	Delegated	9/30/75
Nassau Hospital	Delegated	9/30/75
North Shore University Hospital	Delegated	11/28/75
South Nassau Community Hospital	Delegated	1/19/76
St. Francis	Delegated	1/19/76
Syossett	Delegated	11/28/75

Area XVI

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Attachment 3

Page 3.

Area XVI

<u>Hospital</u>	<u>Status</u>	<u>Effective</u>
Montefiore Hospital and Medical Center	Delegated	2/9/76
Mt. Eden	Delegated	10/20/75
Parkchester	Delegated	12/17/75
Prospect	Delegated	1/29/76
Union Hospital of the Bronx	Delegated	9/16/75

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Attachment 4

The following information will be incorporated into the DSS-2140 and W-220B:

PSRO/Facility-Utilization Review

☐

A. Stay Approved Thru:

☐

B. Stay Denied Effective:

☐

C. Admission Denied



--	--	--

signature

Attachment 5

Notice of Adverse Determination

Date _____

Facility Name _____

Address _____

I. Patient's name _____

Medicaid # _____

Medicare # _____

Social Security # _____

Expiration of Previous Review Period _____

Final Determination Date _____

II. Your case, has been reviewed by _____
and it has been determined that

A. ☐ Admission to this facility was not necessary or appropriate

B. ☐ Continued stay at this facility is not necessary or appropriate

C. ☐ Continued stay at this facility is necessary only pending
placement in an alternate level of care

D. ☐ Other: Specify _____

III. Dr. _____ (Attending Physician) has been notified of this decision
and will contact you to discuss your discharge and plan for any
continued treatment.

IV. As a result of this decision that you no longer require treatment at
the level of care provided by this facility, the Department of Social
Services will cease Medicaid payment for your case on ____/____/____.

V. For Facility UR Committee Determinations:

If you are dissatisfied with the decision of the Department of Social Services to discontinue payment for your care at this facility, you have the right to request a Fair Hearing by notifying the New York State Department of Social Services within 60 days of the date of this letter. To request a Fair Hearing write to:

New York State Department
of Social Services
Fair Hearing Section
1450 Western Avenue
Albany, NY 12243

or telephone (appropriate regional telephone number) _____.

V. For PSRO Determinations:

If dissatisfied with this determination, the patient, attending physician, hospital administrator or their representatives may request a reconsideration from the _____ PSRO. Requests for reconsideration should be in writing and submitted within two months of the date of this notification to:

PSRO Name

Address

VI.

(signature)

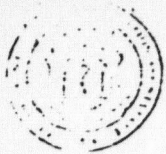
(Title)

NOTE:

1. Each facility or PSRO may choose a notification format, but in each instance the above information shall be included.
2. Local social services shall be sent a copy of the notification form for all long term care adverse decision cases. Notification via the DSS-2140 or W-220B shall suffice for hospital adverse decisions.
3. Each recipient shall receive a notification form including the above information at the time of a _____ adverse determination.

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Exhibit D



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
REGION II
FEDERAL BUILDING
3 FEDERAL PLAZA
NEW YORK, NEW YORK 10007

February 27, 1976

SOCIAL AND REHABILITATION
SERVICE

Mr. Stephen Berger
Commissioner
New York State Department
of Social Services
1450 Western Avenue
Albany, New York 12243

Dear Steve:

This letter represents a follow-up to Secretary Mathews letter of February 4, 1976, which was a response to your letter of January 13 concerning the State's legislative proposals to control Medicaid and public assistance costs.

As the Secretary correctly pointed out, this office has been carefully reviewing the proposals to determine their consistency with Federal requirements. In so doing, we have been mindful that all levels of government are presently grappling with ways to control the runaway costs in the Medicaid program. This effort is particularly significant in States similar to New York where fiscal expenditures in support of a substantial array of optional and mandatory medicaid services are out-growing the State's ability to finance them. Moreover, we are also aware of the existing gap between local county Public Assistance expenditures and their tightening tax base.

All of this does of course require a close examination by the State of its \$4.8 billion Public Assistance Program.

Thus, as we reviewed the Governor's proposals to control Medicaid and Public Assistance costs, we were acutely aware of the State's fiscal problems.

Even so, while many of the Governor's measures to control costs are consistent with Federal statutes and regulations, others are inconsistent and raise questions of compliance.

In the main, the proposed legislation relates to the Medicaid Program. The only change in income maintenance policy is solely in regard to the Home Relief Program over which our office has no jurisdiction.

- Chiropractic services
- Podiatry services
- Physical therapy and related services
- Occupational and Speech Therapy, and Psychologists
- X-Ray services other than performed as part of authorized Dental Care or performed by a medical facility
- Private Nursing
- Elimination of Non-Legend Drugs
- Adult Dental Care

In regard to EPSDT, the regulation in 45 CFR 249.10(a) (iv) specifically states that "eyeglasses, hearing aids, and other kinds of treatment for visual and hearing defects, and at least dental care as is necessary for relief of pain and infection and for restoration of teeth and maintenance of dental health will be available, whether or not otherwise included under the State Plan."

Thus, if you wish to exclude adult dental services, for example, we would recommend that you delete the word "adult" preceding services and indicate that dental services will be solely limited to those as provided under EPSDT. In so doing, the State would satisfy the comparability requirements of 45 CFR 249.10(a)(6) and meet the mandatory EPSDT requirements in 45 CFR 249.10(a)(12).

Most of the following measures raise questions of compliance with the pertinent Federal requirements, and the Secretary is designed to assist you in achieving conformity so that the objectives sought can be achieved.

A. Elimination of Medicaid Coverage for Certain Surgical Procedures

The surgical procedures sought to be eliminated include in-patient hospital services and physicians' services which are mandatory services under Section 1902(a) (13), 45 CFR 249.10 (a) (1), and 1905(a) (1) and (5), 45 CFR 249.10(b) (1) and (5). Most surgical procedures would, thus, be fully covered both as to hospital cost and physicians cost. Surgical procedures would also be generally covered whether performed in a hospital or in a doctor's office.

A blanket elimination of all surgery that is not immediately necessary to save life, relieve severe pain or avoid disability entails a reduction in mandated services that is not authorized in the Social Security Act or Federal regulations. Failure to fully provide services which are federally mandated would place New York out of compliance.

Thus, we would recommend that the proposed elimination of "elective surgery" should be carefully examined with respect to medical necessity. For example, it is not reasonable to consider all but emergency service elective, even though there is leeway for scheduling. A distinction should be made between "elective" and non-acute or non-emergency. Some care is truly elective but, in other cases, for instance, non-acute gall-bladder disease, the elective is only in relation to scheduling. Moreover, elimination of certain surgical procedures in the manner of elective surgery is a violation of Medicaid regulation 45 CFR 249.10(a) (5) (1).

B. Second Medical Opinion as Prerequisite of Elective Surgery

The elimination of elective or deferrable surgery in all cases unless two doctors certify that a wait of six months or more will jeopardize life or essential function appears sound and we have no objection that would prohibit its implementation. Significantly, the Congressional Sub-committee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, recently released a study on unnecessary surgery. That report contended that 2.38 million surgical procedures were unnecessarily performed in 1974 at a cost to the American public of \$3.92 billion.

While the legislation in itself does not preclude compliance with Federal requirements and attempts to place some control to avoid unnecessary surgery, implementing procedures would require careful scrutiny to avoid a cumbersome process.

C. Limitation of Pre-surgical Hospital Stays to One-Day,
Inpatient Hospital Stays to 20 Days, and Broadening
of Authority of Budget Director

First, the limitation of reimbursement for in-patient hospital stays to 20 days raises a question on compliance with Federal regulations, but we would find the measure more acceptable if reimbursement could be extended because of medical necessity beyond the 20 days. Thus, the State has the option of implementing the proposed legislation if the Legislature takes positive action.

Second, the measure to provide the Budget Director with the authority to suspend all in-patient hospital Medicaid reimbursement past 20 days appears to be obviated by approval of the foregoing measure limiting the stays to 20 days. Otherwise, the measure would raise an issue of Federal compliance since the provisions would violate Section 1902(a) (5) which provides that State plans must provide for a single State agency to administer or supervise all aspects of the State plan except that eligibility determination may be made by the State Public Assistance agencies. Thus, the delegation of important authority to the Budget Director to suspend reimbursement past 20 days would raise a compliance issue.

Third, limitation in reimbursement for pre-surgical in-patient hospital stay for one day would, in itself, raise a question of compliance with 45 CFR 249.10(a) (5) (i). That regulation provides that medical assistance must be "sufficient in amount, duration and scope to reasonably achieve their purpose." We believe that there are occasions when a one-day preoperative hospital stay would not be sufficient in duration to achieve its purpose for the patient.

However, it appears to us that the overall 20-day limitation would serve as a satisfactory limit on pre-surgical hospital days.

D. Requirement that Skilled Nursing Facilities (SNF) Become
Medicare Providers and Application and Utilization of
Medicare as Condition of Eligibility for Medicaid

This requirement relating to SNF participation in Medicare as a condition for participation in the Medicaid program raises a question of compliance with Federal requirements since the policy would be inconsistent with Sections 1902(a) (23), 1902 (a) (33) (B), and 1910 of the Social Security Act.

It is the intent of this foregoing statute that a facility's participation in the Title XVIII program is not a prerequisite to participation under the Title XIX program.

The second part of the Governor's bill regarding application and utilization of Medicare benefits as a condition of eligibility is inconsistent with the requirements in Section 1902 (a) (1) (17) and 45 CFR 248.2. These standards bar the imposition of a condition of eligibility for Medicaid additional to those outlined in the statute and governing regulations.

E. In-patient Hospital Services

We have some serious reservations concerning this proposal, which would modify the existing hospital reimbursement rate, and we have informed you of the specifics of our concerns by letter of February 10, 1976.

F. Rates of Payment for Out-patient Departments to Emergency Room Services During January 1, 1976 to March 31, 1977 Set at 10% Below 1975 Rates

Section 1902(a) (3) states that the State plan shall provide such methods and procedures to "assure that payments are not in excess of reasonable charges consistent with efficiency, economy and quality of care." Regulations implementing this section provide the State with the upper limits of charges for which the State can expect Federal reimbursement. 45 CFR 250.30(b). That regulation also provides that the "State Agency may pay less than the upper limits." With regard to non-institutional services, the regulations provide that the upper limits for payment shall be customary charges which are reasonable. 45 CFR 250.30(b) (3) (b). If the rate of payment set by the State for these services is less than reasonable customary charges, therefore, the rates are within the upper limits and thus are acceptable. For out-patient hospital services and clinic service, in particular, schedules of payment are not to exceed the combined payments received by providers and beneficiaries under Title XVIII (45 CFR 250.30 (b) (3) (ii). That regulation provides that "Schedules will be acceptable if within the upper limits" either on a facility by facility basis or on the basis of average payment.

Thus, if New York's rates are within these upper limits, they are acceptable.

G. Rates of Payment of Long Term Care Facilities to be Kept at 1975 Levels for January 1, 1976 to March 31, 1977

Federal requirements provide only upper limits in regard to requirements for a State in setting rates for nursing homes. These upper-limits are also reasonable customary charges or Medicare rates. The State is entitled to provide less than full upper limit fee schedule.

Therefore, our only objection to this rate freeze would be on the basis of a finding that such rates would make it impossible for Medicaid recipients to obtain these services to the extent that the general population is able to obtain them. However, effective July 1, 1976 payment of skilled nursing facilities will be "on a reasonable cost related basis, as determined in accordance with methods and standards which shall be developed by the State on the basis of cost finding methods approved and verified by the Secretary" Social Security Act, Section 1902(a)(13)(E). Reasonable cost may be found by reference to 1975 cost levels.

If you would like clarification and/or more information regarding these comments, feel free to call us.

Sincerely,

William Toby
Acting Regional Commissioner

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Exhibit E



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
REGION II

FEDERAL BUILDING
26 FEDERAL PLAZA
NEW YORK, NEW YORK 10027
March 29, 1976

OFFICE OF THE
REGIONAL DIRECTOR

Honorable Hugh L. Carey
Governor of the State of New York
Executive Chambers
Albany, New York 12224

Dear Governor Carey:

We are writing in reference to Senate Bill 7287 and Assembly Bill 9257 containing significant and substantial changes in Medicaid reimbursement and rate-setting procedures. The basic intent of these bills as we understand them, is to implement controls on medical assistance and public assistance expenditures.

As you know, during the past year in the face of rising program costs and mounting evidence of erroneous expenditures, HEW has itself placed renewed emphasis on increasing the requirements for State accountability of Medicaid program operations.

To assist in this effort, a number of new federally prescribed control measures have been implemented. These control measures include providing for Professional Standards Review Organizations (PSRO), and a Medicaid Quality Control program for recipient eligibility. These efforts represent only a portion of the necessary program controls, leaving states with wide latitude in providing policy leadership in such areas as provider fraud and abuse, claims processing problems, abuses by nursing homes and other providers, third party liability, and duplicate claims, all of which contribute to erroneous procedures.

In light of these concerns, the Department of Health, Education, and Welfare, in general, supports, the Legislative action embodied in S-7287 and A-9257 designed to strengthen the administration of the Medicaid program and curb the rapid rise in expenditures. Our previous support for this legislation was conveyed by letter of February 27, 1976, to Social Services Commissioner Stephen Berger from Acting Regional Commissioner of Social and Rehabilitation Service William Toby (copy enclosed).

Despite our general support, however, we wish to call to your attention those parts of the bill which do not conform to Federal requirements. Specifically, the following areas of concern should be given additional attention before implementation to achieve your objective:

1) Limitation on Surgery

Section 3 of the law, amending section 365-a of the Social Services Law would significantly limit surgical benefits reimbursed under Medicaid. The surgical procedures so limited are provided as "inpatient hospital services" or "physicians services" which are both mandatory services under a state Medicaid program (cf. sections 1902(a)(13) and 1905(a)(1) and (5) of the Act). Under Medicaid regulations 1/ "inpatient hospital services" are defined as "those items and services ordinarily furnished by the hospital for the care and treatment of inpatients ..." (emphasis supplied). "Physician services" are defined 2/ in the Medicaid regulations as "services provided, within the scope of practice of his profession as defined by State law ...". Certain surgical procedures -- outside the scope of the limiting amendment -- would be 'ordinarily provided' or still within general state defined physician practices. Accordingly, some surgical procedures and physician services outside the scope of the New York amendment must be provided to Medicaid recipients. Failure to provide these procedures which are mandated by the Act, and Medicaid regulations, would bring into question New York's compliance with federal law. This conflict with federal law would not escape consideration by third parties in any litigation against the State with respect to the surgical cut-backs. The limitations on surgical procedures also are inconsistent with the Medicaid regulation at 45 CFR 249.10(a)(5)(i) which provides, in pertinent part,:

"The State may not arbitrarily deny or reduce the amount, duration or scope of such services for an otherwise eligible individual solely because of the diagnosis, type of illness or condition. Appropriate limits may be placed on services based on such criteria as medical necessity or those contained in utilization or medical review procedures."

The wording of the New York law eliminating elective and deferrable surgery in all cases unless two doctors certify that a wait of six months or more will jeopardize life or essential function makes reimbursement for mandatory hospital and physician services contingent on diagnosis and type of illness or condition (contrary to the above regulation). Accordingly, the provision in Section 3 limiting the availability of surgical procedures to specified conditions seems an arbitrary blanket exclusion of mandated services that goes beyond medical necessity or utilization review and violates 45 C.F.R. 249.10(a)(5)(i). In addition such exclusion of beneficial surgical procedures may violate the general requirement of Section 1902(a)(19) that

1/ 45 CFR 249.10(b)(1).

2/ 45 CFR 249.10(b)(5).

all state plans provide that "care and services under the plan will be provided in a manner consistent with simplicity of administration and the best interests of the recipients."

2) Single State Agency

Section 1902(a)(5) of the Social Security Act requires the state Medicaid plan designate a "single state agency" to administer or supervise administration of the Medicaid program. The federal regulations ^{3/} indicate that the single state agency "will not delegate to other than its own officials its authority for exercising administrative discretion in the administration or supervision of the plan including the issuance of policies, rules, and regulations on program matters". In New York, the single state agency is the Department of Social Services.

The integrity required of the single state agency is violated in certain provisions of the New York amendments. The amendment limiting surgical procedures reimbursed under Medicaid provides, for example, that the Health Department shall issue and implement policies which establish when surgery will be reimbursable, and how long a patient can stay in hospital prior to surgery. Health Department activity would not result from a discretionary delegation from the single state agency with the latter retaining ultimate authority, but rather through statutory mandate. Therefore, the single state agency -- through this legislation -- would be stripped of its authority to maintain final control over determinations of amount, duration, and scope of medical services. A similar erosion of single state agency administrative authority and responsibility is effected in section 4 of the amended New York statute which sets a 100 day and a 20 day limitation on patient stays in various health care facilities. This limitation without the exception therein -- that prior health commissioner approval can extend the time -- would clearly violate those same federal requirements referred to in the above discussion on the surgery restrictions. However, the exception itself is in violation of Medicaid requirements as it grants an unqualified administrative function to the health commissioner, e.g. ultimate authority for this aspect of Medicaid program administration without single state agency control.

A similar violation of the single state agency requirement is found in amendment section 6, subsection 2. This provision requires that the single state agency ("social services officials") officials "shall withhold payment for such services upon the certification of the commissioner of health that such care is inappropriate or unnecessary" (emphasis supplied). Common language usage indicates that under this provision Health -- not the single state agency -- has the ultimate authority with respect to Medicaid reimbursement.

^{3/} 45 CFR 205.100(b)(1)

This procedure clearly destroys the administrative integrity of the single state agency, thus violating section 1902(a)(5) of the Act. The Public Health Law has been amended 4/ to grant such authority to the Health Commissioner and provide for his issuance of rules and regulations affecting this area required to be administered, and regulated, under federal statute and regulations, by the single state agency.

3) Medicare as a Condition of Eligibility

Section 5(b) of the amendment requiring eligible persons to fully utilize benefits under Title XVIII, is acceptable provided that it is clearly understood that medicare benefits are to be considered a resource, when available, rather than a condition of eligibility. The state cannot add conditions of eligibility for Medicaid additional to those outlined in the Federal law in section 1902(a)(10)(17), 45 CFR 248.2. Accordingly, the amendment would violate federal law if it makes Medicaid eligibility contingent on application for Medicare.

4) Medicare Qualification for Skilled Nursing Facilities

With respect to section 4(b) of the Amendments, which defines nursing homes as those facilities "that qualify as providers in the Medicare program", we now understand that the Medical Services Administration and the Office of General Counsel have determined that the Federal laws and regulations do not prevent the state from requiring that all skilled nursing facilities which wish to participate in the Medicaid program must qualify for Medicare. Accordingly, this Department no longer objects to section 4(b).

5) Potential Conflict with PSRO Legislation

Sections 6 and 8 of Section 7287-A pose a potential conflict with Title XI, Part B of the Social Security Act -- The Professional Standards Review Organization legislation.

Specifically, the above named sections could vest final review authority in the State Commissioner of Health over determinations of medical necessity and appropriateness of services provided under Medicaid, where a PSRO has assumed such authority with the approval of the Secretary of the Department of Health, Education and Welfare. In the latter instance, the PSRO Act clearly provides that such determinations are to be conclusively made by the PSRO; no payment of Federal funds may be made where the PSRO disapproves of such services subject to its review, and so notifies the paying agency. Furthermore, section 1164 of the Social Security Act requires the application of the provisions of that Act to the operation of a state's Medicaid plan or program.

4/ Section 8(d) of the amendments.

Although the initial designations of PSROs are to be on a conditional basis, the Secretary has determined that, during the conditional phase, PSRO review of medical necessity and appropriateness is to be final. Accordingly, determinations of medical necessity by the State must be subordinated in any case under the jurisdiction of the PSRO.

If authoritative state review were to be imposed together with PSRO review, questions could be raised of compliance with section 1164, and of Federal reimbursement of duplication of review since the Secretary has also determined that Federal funding for parallel review activities shall be disallowed.

As far as New York State is concerned, there are conditionally-designated PSROs for nine of the State's seventeen PSRO areas. These nine PSROs have assumed review authority in forty-six hospitals in New York State and will be assuming this authority in additional hospitals this year. Further, the President's budget calls for PSRO coverage of all PSRO areas by the end of fiscal year 1977.

We hope these documents are useful to you. If you have any questions, please feel free to contact me.

Sincerely,

Bernice L. Bernstein
Bernice L. Bernstein
Regional Director

cc: JHS
JRS
SSA/3 HII

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
THE MEDICAL SOCIETY OF THE STATE OF :
NEW YORK, a New York not-for-profit :
corporation, MORTON M. KOFF, M.D., :
MILTON ROSENBERG, M.D., and JANE DOE, :

Index No. 76 Civ.

Plaintiffs,

-against-

PHILIP TOIA, as Commissioner of the :
Department of Social Services of the :
State of New York and ROBERT P. WHALEN, :
M.D., as Commissioner of the Department :
of Health of the State of New York, :

Defendants. :

: AFFIDAVIT IN SUPPORT
: OF APPLICATION FOR
: ORDER TO SHOW CAUSE

-----x
STATE OF NEW YORK)
COUNTY OF SUFFOLK) ss:

MILTON ROSENBERG, being duly sworn, deposes and
says:

1. I am a doctor of medicine, duly licensed to
practice under the laws of the State of New York and one of
the plaintiffs herein. I make this affidavit in support of the
application of all the plaintiffs herein for an order directing
the defendants Commissioner of Social Services and Commissioner
of Health to show cause why an order should not be entered
herein staying the effective date of Sections 3 and 4 of
Chapter 76 of the Laws of New York, 1976 and enjoining said
defendants pending the disposition of this action from enfor-
cing or implementing those Sections and the regulations

or instructions issued pursuant thereto.

2. The grounds for plaintiffs' application are that Sections 3 and 4 of Chapter 76 and the regulations issued pursuant thereto eliminate the availability of reimbursement for certain types of deferrable surgical procedures for persons otherwise qualified for such procedures under the provisions of Title XIX of the Federal Social Security Law, 42 U.S.C. §§1396 et seq. ("Medicaid") in violation of the Federal statute.

As a result the State statute unlawfully and unconstitutionally interferes with a physician's right to practice medicine according to his best medical judgment and with the rights of Medicaid patients to be treated according to the best medical judgment of his or her attending physician to the irreparable injury of both patient and physician.

3. As set forth in the Complaint herein, I am a member of plaintiff The Medical Society of the State of New York (the "Medical Society"). I am also a member of the Suffolk County Medical Society and my specialization in the practice of medicine is Obstetrics and Gynecology, in which I am Board certified. I presently hold the position of Director of Obstetrics and Gynecology at Brookhaven Memorial Hospital in Patchogue, Long Island and maintain a private office at 485 New North Ocean Avenue, Patchogue, Long Island. In addition, I am an Associate Clinical Professor at the Medical School of Stony Brook College, a Fellow of the American College of Obstetrics

and Gynecology and a Diplomate of the American Board of Obstetrics and Gynecology. In the course of practicing my profession, I have occasion to treat patients covered by Medicaid, as well as patients not covered by that program, and to recommend and perform surgical procedures with respect to such patients.

4. I have recently read Chapter 76 of the Laws of the State of New York, 1976, a copy of which is annexed to the affidavit of Dr. Koff as Exhibit A, together with the currently effective regulations of the Department of Health and a draft Administrative Letter of the Department of Social Services proposed to be promulgated pursuant thereto, copies of which are annexed to the affidavit of Dr. Koff as Exhibits B and C, respectively. The statute, regulations and Administrative Letter provide, as here relevant, that the defendant Commissioner of Social Services will no longer certify for payment under Medicaid any claims for deferrable in-patient surgical procedures or services of a physician related thereto except when two physicians certify to the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function or cause severe pain to the patient or except when defendant Commissioner of Health permits such procedures and services on the basis of "medically indicated risks factors". In the event that such surgical procedures cannot be compensated pursuant to Medicaid, most, if not all, Medicaid patients will be unable to have such procedures performed and physicians like

myself will be unable to carry them out except on an ad hoc charitable basis.

5. In the course of practicing my profession and within the scope of my practice under state law, I and numerous other members of the Medical Society have occasion to recommend and to perform surgery for patients qualified for Medicaid both on an inpatient and outpatient basis in numerous situations not excepted by defendant Commissioner of Health in which two doctors could not be expected to certify that the surgery could not be deferred for six months or more without jeopardizing life or essential function or causing severe pain. Besides being generally available to other non-Medicaid patients as part of the ordinary practice of medicine within New York State, these surgical procedures are also medically necessary and desired by the patients for perfectly legitimate reasons, including the alleviation of continued moderate pain, the elimination of serious emotional and psychological trauma and, on occasion, difficulties in obtaining gainful employment.

6. The condition of plaintiff Jane Doe herein is an immediate example of the effect upon Medicaid patients of Chapter 76 and the regulations issued pursuant thereto. Plaintiff Jane Doe is a middle-aged mother of several children who is a Medicaid patient and who has a long-standing relationship as the patient of a physician member of the Brookhaven Memorial Hospital staff. Her chief symptom is dysfunctional bleeding from an enlarged uterus which is approximately twice its normal size, which bleeding occurs on approximately a

bi-weekly basis. Her physician recommends that she undergo a dilatation and curettage, a surgical procedure normally performed in these circumstances, and which, prior to enactment of Chapter 76, would have been covered by Medicaid. However, because her condition does not threaten life, essential function or cause severe pain, the operation is not covered under Chapter 76 and she is presently unable to obtain relief from her physician. If the injunction requested herein is not granted, plaintiff Jane Doe will be forced to continue to suffer the abnormal bleeding indefinitely, which may result in even more serious complications at a later date, to her irreparable injury.

7. Following are examples of other disorders which require surgery and for which I would normally recommend surgical procedures which will no longer be available to Medicaid patients under Chapter 76 because they do not threaten life or essential function or cause severe pain:

(1) cystocoele or dropping of the bladder - this condition results from deterioration of the ligaments which surround the bladder and are necessary to retaining urine in the bladder. The chief symptoms are loss of urine due to the minor muscle spasms that occur when the patient sneezes, coughs or laughs, and consequent odor and staining. This disorder frequently causes emotional trauma, disruption of social life and interference with employment. Because these symptoms never improve without medical intervention, where they exist, I normally recommend surgery to correct the disorder. However,

under Chapter 76, such surgery will no longer be available to Medicaid patients.

(2) condyloma accuminata -- this condition results from the development of venereal warts in and around the vagina and the vulva. Such warts are extremely unsightly and often cause irritation, itching and interruption of normal sexual activities, leading to emotional trauma for the patient. In some instances these lesions are so large as to require surgical removal and cannot be treated medically. Although a surgical procedure would normally be recommended to relieve these symptoms, such surgical procedures will no longer be covered for Medicaid patients under Chapter 76.

(3) ovarian cysts - although some are malignant and of course covered under Chapter 76, many such cysts are benign at the initial testing stage, but could become malignant after a period of months or years. To prevent the development of malignancy, I would, where the diagnosis warranted it, perform surgery as a matter of preventive medicine. However, because a benign tumor does not threaten life, or essential function or cause severe pain, I will be unable under Chapter 76 to provide such care for Medicaid patients.

WHEREFORE, for the reasons set forth herein and in the accompanying complaint, I respectfully request this Court to enter an order directing the defendants Commissioner of Social Services and Commissioner of Health to show cause why an order should not be entered staying the effective date of Sections 3 and 4 of Chapter 76 of the Laws of New York, 1976 and enjoining said defendants from enforcing or implementing those Sections of

the recently enacted Chapter 76 of the Laws of New York, 1976,
and regulations issued pursuant thereto.

Sworn to before me this
29 day of July, 1976

Annie P. Niquet
Notary Public

ANNIE P. NIQUET
NOTARY PUBLIC, State of New York
No. 52-2895100, Suffolk County
Term Expires March 30, 1977

NILTON ROSCONE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE,

Plaintiffs,

-against-

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P. WHALEN,
M.D., as Commissioner of the Department
of Health of the State of New York,

Defendants.
-----x

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: Index No.

: AFFIDAVIT IN SUPPORT
: OF APPLICATION FOR
: ORDER TO SHOW CAUSE

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

CHARLES P. SIFTON, being duly sworn, deposes and
says:

1. I am a member of the law firm of LeBoeuf, Lamb,
Leiby & MacRae, attorneys for the plaintiffs in this proceed-
ing. I make this affidavit in support of the application of
all the plaintiffs herein for an order directing the defendants
Commissioner of Social Services and Commissioner of Health to
show cause why an order should not be entered herein staying
the effective date of Sections 3 and 4 of Chapter 76 of the
Laws of New York, 1976 and enjoining said defendants pending
the disposition of this action from enforcing or implementing
such sections and the regulations issued pursuant thereto.

2. The purpose of this affidavit is to bring to the Court's attention the opinions of the Regional Director of Region II of the Department of Health, Education, and Welfare ("HEW") with respect to the conflicts between Sections 3 and 4 of Chapter 76 and the Federal Medicaid Statute. These opinions were expressed by the Regional Director to the appropriate New York State authorities prior to the enactment of Chapter 76 in a letter dated February 27, 1976 to Mr. Stephen Berger, then Commissioner of the New York State Department of Social Services (the "Berger letter"), and a letter dated March 29, 1976 to the Honorable Hugh L. Carey, Governor of the State of New York (the "Carey letter"). Copies of these letters have been furnished to my office by the Regional Office of HEW and are annexed to the affidavit of Dr. Morton Koff, submitted herewith, as Exhibits D and E, respectively.

3. The primary conflicts between the Federal Medicaid statutes and Chapter 76 are set forth in the following passage from the Carey letter (at p. 2 of Exhibit E):

"Section 3 of the law, amending section 365-a of the Social Services Law would significantly limit surgical benefits reimbursed under Medicaid. The surgical procedures so limited are provided as 'inpatient hospital services' or 'physicians services' which are both mandatory services under a state Medicaid program (cf. sections 1902(a)(13) and 1905(a)(1) and (5) of the Act [42 U.S.C. §1396 *et seq.*]). Under Medicaid regulations 1/ 'inpatient hospital services' are defined as 'those items and services ordinarily furnished by the hospital for the care and treatment of inpatients...' (emphasis supplied). 'Physicians services' are defined 2/ in the Medicaid regulations as 'services provided, within the scope of practice of his profession as defined by State law...'. Certain surgical procedures -- outside the scope of the limiting amendment -- would be 'ordinarily provided' or still within general state defined

procedures would, thus, be fully covered both as to hospital cost and physicians cost. Surgical procedures would also be generally covered whether performed in a hospital or in a doctor's office.

"A blanket elimination of all surgery that is not immediately necessary to save life, relieve severe pain or avoid disability entails a reduction in mandated services that is not authorized in the Social Security Act or Federal regulations. Failure to fully provide services which are federally mandated would place New York out of compliance."

5. These interpretations of the Federal Medicaid statute by officials directly charged with administering them are, of course, entitled to great weight. At the same time HEW has taken no steps of which I am aware to correct the situation by commencing compliance proceedings or otherwise.

6. Plaintiffs have no adequate remedy at law.

7. This application is being brought on by order to show cause rather than by motion because of the need of plaintiff Jane Doe for immediate relief from the irreparable harm being caused her by reason of her inability to obtain medically necessary surgery under the terms of Chapter 76. Plaintiff physicians are likewise confronted immediately with the problem of advising Medicaid patients whose conditions may require deferrable surgery as to availability of Medicaid reimbursement for such procedures.

WHEREFORE, for the reasons set forth herein and in the accompanying affidavits, complaint and memorandum of law, I respectfully request this Court to enter an order directing the defendants Commissioner of Social Services and Commissioner of Health to show cause why an order should not be entered staying the effective date of Sections 3 and 4 of Chapter 76 of the

United States District Court

FOR THE

EASTERN DISTRICT OF NEW YORK

CIVIL ACTION FILE NO. _____

THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE,

Plaintiffs

v.

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P. WHALEN,
M.D., as Commissioner of the Department
of Health of the State of New York,

Defendants.

SUMMONS

To the above named Defendants :

You are hereby summoned and required to serve upon

LeBoeuf, Lamb, Leiby & MacRae

plaintiff's attorney , whose address

140 Broadway, New York, New York 10005

an answer to the complaint which is herewith served upon you, within 20 days after service of this
summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be
taken against you for the relief demanded in the complaint.

Clerk of Court.

Deputy Clerk.

Date:

[Seal of Court]

NOTE:—This summons is issued pursuant to Rule 4 of the Federal Rules of Civil Procedure.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE,

Plaintiffs,

- against -

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P. WHALEN,
M.D., as Commissioner of the Department
of Health of the State of New York,

Defendants.
----- x

COMPLAINT FOR
DECLARATORY JUDGMENT
AND INJUNCTIVE RELIEF

Plaintiffs, by their attorneys, LeBoeuf, Lamb,
Leiby & MacRae, for their complaint herein, respectfully allege
as follows:

PRELIMINARY STATEMENT

1. This is an action for preliminary and permanent
injunctive relief and for a declaratory judgment brought by The
Medical Society of the State of New York (the "Medical Soci-
ety"), Morton M. Koff and Milton Rosenberg, doctors of medicine
licensed to practice under the laws of New York and Jane Doe, a
resident of Long Island, New York who is a patient entitled to
medical assistance under the joint Federal and State program
for medical assistance provided for under Title XIX of the
Social Security Act, 42 U.S.C. §1396 et seq. ("Medicaid").

2. On March 30, 1976, the Governor of the State of New York signed into law Chapter 76 of the Laws of New York, 1976 ("Chapter 76"), substantially, unconstitutionally and illegally limiting the authority of defendant Philip Toia, as Commissioner of Social Services of the State of New York, to certify for payment requests for reimbursement for various types of surgical procedures and inpatient hospital care under Medicaid, pursuant to regulations to be issued by defendant Robert P. Whalen, M.D., as Commissioner of Health.

3. Section 3 of the new law eliminates all benefits for surgery for Medicaid patients other than (1) benefits "for emergency or urgent surgery for the alleviation of severe pain, for immediate diagnosis or treatment of conditions which threaten disability or death if not promptly diagnosed or treated"; (2) benefits for certain other surgical procedures "as established by the state commissioner of health on the basis of medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with surgical intervention"; and (3) other "deferrable" surgical procedures based on the likelihood, established by two written opinions, that deferral of the surgical procedures for six months or more "may jeopardize life or essential function, or cause severe pain". In addition, the new law limits pre-operative hospital care for reimbursable surgical procedures to a maximum of one day, except with regard to specific surgical procedures identified by the State Commissioner of Health as requiring a longer period of pre-operative hospital care, and limits benefits for hospital care to a maximum of twenty

days, unless it is determined that a longer period of hospital care is required in particular cases in accordance with procedures and criteria established by the Commissioner of Health "to preserve life or to prevent substantial risks of continuing disability."

4. Acting pursuant to Chapter 76, defendants Toia and Whalen have violated and continue to violate Title XIX of the Social Security Act and Federal regulations issued pursuant thereto, the Supremacy Clause embodied in Article VI of the United States Constitution, the First, Fifth, Ninth and Fourteenth amendments to the United States Constitution and the Constitution of the State of New York.

5. The effect of defendants' conduct pursuant to Chapter 76 has been to deny to certain Medicaid patients, including plaintiff Jane Doe, certain deferrable surgical procedures which would otherwise be furnished to them by licensed practitioners of medicine within the scope of their practice as defined by State law and to interfere with the practice of medicine of doctors, including plaintiffs Rosenberg and Koff and other members of plaintiff Medical Society, who would otherwise recommend and carry out such deferrable surgical procedures with respect to their Medicaid patients, thus jeopardizing their continued ability to provide high quality health care to the low income and indigent residents of New York State.

FIRST CAUSE OF ACTION

Plaintiffs

6. Plaintiff Medical Society is a New York not-for-profit corporation having its principal place of business at 420 Lakeville Road, Lake Success, New York and is organized for the purpose of providing administrative assistance to its 28,000 physician members and of enhancing "the delivery of medical care of high quality to all people in the most economical manner; [and] to promote the betterment of community health". Bylaws, Article I.

7. Plaintiff Milton Rosenberg is a Doctor of Medicine, duly licensed to practice under the laws of the State of New York and a member of plaintiff Medical Society. Plaintiff Rosenberg specializes in obstetrics and gynecology and maintains an office for his practice at 485 New North Ocean Avenue in Patchogue, Long Island and treats substantial numbers of patients covered by Medicaid as well as patients not covered by that program.

8. Plaintiff Morton M. Koff is a Doctor of Medicine, duly licensed to practice under the laws of the State of New York and a member of plaintiff Medical Society. Plaintiff Koff specializes in the practice of family medicine and maintains an office for his practice at 801 E. Park Avenue in Long Beach, Long Island and treats substantial numbers of patients covered by Medicaid as well as patients not covered by that program.

9. Plaintiff Jane Doe is a low income resident of Long Island, New York who is qualified by reason of her financial status for medical assistance under the Medicaid Program. She is a middle-aged mother of several children who has a

long-standing relationship as the patient of a physician member of the staff of Brookhaven Memorial Hospital, Patchogue, Long Island. Her chief symptom is dysfunctional bleeding from an enlarged uterus which is approximately twice its normal size, which bleeding occurs in unusual volume on approximately a bi-weekly basis. Her physician recommends that she undergo a dilatation and curettage, a surgical procedure normally performed in these circumstances, and which, prior to enactment of Chapter 76, would have been covered by Medicaid. However, because her condition does not threaten life, essential function or cause severe pain, the operation is not covered under Chapter 76 and she is presently unable to obtain relief from her physician. If the injunction requested herein is not granted, plaintiff Jane Doe will be forced to continue to suffer the abnormal bleeding, together with the physical discomfort and emotional trauma caused by her condition, indefinitely, to her irreparable injury.

Defendants

10. Defendant Philip L. Toia is, and at all times relevant to this proceeding was the Commissioner of Social Services of the State of New York. The New York State Department of Social Services, under defendant Toia's direction, has and threatens to limit certification for payment for surgical procedures pursuant to Chapter 76 to otherwise qualified Medicaid patients.

11. Defendant Robert P. Whalen, M.D., is and at all times relevant to this proceeding was, the Commissioner of Health of the State of New York. The Department of Health,

under defendant Whalen's direction, has acted pursuant to Chapter 76 to issue regulations purporting to limit surgical procedures for which defendant Toia may certify payment under Medicaid.

JURISDICTION AND VENUE

12. This action arises under the Medicaid Act, 42 U.S.C. §1396 et seq. and the regulations promulgated thereunder, 42 U.S.C. §1983, Article VI of the United States Constitution and the First, Fifth, Ninth and Fourteenth Amendments thereto, the New York State Constitution, the New York Social Services Law and Public Health Law and the regulations promulgated pursuant thereto.

13. Jurisdiction is vested in this Court under 28 U.S.C. §§1331, 1343, 2201 and 2202 and principles of pendent jurisdiction. The amount in controversy exceeds the sum of \$10,000 exclusive of interest and costs.

14. Venue lies in this District pursuant to 28 U.S.C. §1391.

STATEMENT OF FACTS

15. The Federal government currently provides monies to states for the provision of medical assistance to qualified low income and indigent persons pursuant to a joint Federal-State program known as Medicaid governed by Title XIX of the Social Security Act, 42 U.S.C. §1396 et seq., and the regulations promulgated thereunder.

16. The Medicaid Act requires that any state which accepts monies from the Federal government pursuant to the Medicaid Program have in effect a state plan providing that

qualified low income and indigent persons be entitled to payment for inpatient hospital services and physicians' services furnished by licensed practitioners within the scope of their practice as defined by State law. 42 U.S.C §1396d(a)(1) and (5). Federal regulations pursuant thereto provide that the state plan must cover "inpatient hospital services" defined as "those items and services ordinarily furnished by the hospital for the care and treatment of inpatients provided under the direction of a physician" as well as "physicians' services" defined as "those services provided, within the scope of his practice as defined by State law, by or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy." 45 C.F.R. §249.10(b)(1) and (b)(5). Federal regulations further provide that:

"The State may not arbitrarily deny or reduce the amount, duration or scope of such services for an otherwise eligible individual solely because of the diagnosis, type of illness or condition." 45 C.F.R. §249.10(a)(5)(i).

17. New York State has, since 1966, had in effect a State Medicaid Program purporting to comply with all Federal requirements and authorizing and directing the acceptance of Federal funds under the Federal Medicaid Program and their disbursement to qualified persons for medical assistance certified as proper for payment by the Department of Social Services. New York Social Services Law, Title 11. Included in such program has been provision for certification and payment for surgical procedures and physicians services "necessary to prevent, diagnose, correct or cure conditions ... that cause acute suffering, endanger life, result in illness or infirmity, interfere with...[the patient's] capacity for normal activity,

or threaten some significant handicap...". Social Services Law §365-a.

18. On March 30, 1976, the Governor of New York State signed into law Chapter 76 amending Section 365-a of the Social Services Law, significantly limiting the authority of defendant Toia to certify for payment certain surgical procedures theretofore paid under the State program. Thus Section 3 of the new law, after directing that "medical assistance shall not include any in-patient surgical procedures or any care, services or supplies related to such surgery other than those authorized by this subdivision," eliminated all deferrable surgery other than (1) surgery that, based on two written opinions, may not be deferred for six months or more without jeopardizing life or essential function or causing severe pain and (2) certain other surgical procedures designated by the Commissioner of Health on the basis of "medically indicated risk factors" and medically necessary surgery where delay would substantially increase the medical risk associated with surgical intervention.

19. Pursuant to such authority, defendant Whalen has promulgated regulations eliminating reimbursement under Medicaid for deferrable surgery, except for five specified types of surgical procedures, unless such surgery cannot be deferred for six months or more without jeopardizing life or essential function or causing severe pain, and limiting hospital care according to criteria established by the Commissioner of Health as required by Chapter 76.

20. Plaintiffs Rosenberg, Koff and numerous others of the members of plaintiff Medical Society have, on a regular basis as part of the ordinary practice of their profession and within the scope of practice of that profession as defined by State law, occasion to recommend and perform medically necessary surgery for patients qualified for Medicaid, both on an inpatient and outpatient basis, in numerous situations not excepted by defendant Whalen's regulations in which two doctors can not be expected to certify that the surgery could not be deferred for six months or more without jeopardizing life or essential function or causing severe pain. Included among such situations are the following:

21. On numerous occasions plaintiff Koff has had and expects to have in the future qualified Medicaid patients suffering from hemorrhoids, a rupturing of veins in the anal canal, causing swelling and, frequently, minor bleeding. This disorder usually results in itching and minor physical discomfort and may cause embarrassing staining of the patient's clothing in the vicinity of the anus. The patient's condition can be corrected by inpatient surgery. However, deferral of such surgery for six months or more would in most cases in no sense jeopardize life or essential function of the patient or cause him severe pain.

22. Dr. Koff also on a regular basis has occasion to be consulted and expects in the future to be consulted by qualified Medicaid patients suffering from benign tumors of the skin which present unsightly distortions of their facial features or other members. These complaints as well do not, in the usual case, cause more than minor discomfort. Nor do they

jeopardize the patient's life or essential function although they frequently result in social embarrassment and social ostracism and, on occasion, difficulties in obtaining employment and social company. The elimination of these grossly unsightly tumors may, however, be accomplished by modern surgery on either an inpatient or outpatient basis.

23. Plaintiff physicians also as part of their authorized practice of medicine under New York State law have continuous occasion to diagnose and treat lipoma or other benign tumors of the vulva suffered by Medicaid patients, a disorder which does not ordinarily cause pain except during sexual intercourse performed in a manner which creates pressure on the tumor. Life and essential function are not jeopardized since sexual intercourse can still be performed and reproduction can still occur, and pain can be avoided and is not severe. Nevertheless, surgical procedures are commonly performed to alleviate the condition because of the serious emotional trauma which frequently results from the difficulties it creates in sexual relations.

24. A not uncommon medical condition witnessed by plaintiff Rosenberg in his specialization of gynecology and obstetrics is cystocele or dropping of the bladder. Symptoms of this condition, resulting from a relaxation of ligaments retaining urine in the bladder, include loss of urine, consequent odor and staining following minor muscle spasms associated with sneezing, coughing or laughing. The condition is in no sense life threatening, typically causes no pain, nor does it jeopardize any essential function. However, the frequently resulting emotional trauma, social and economic

dislocations and embarrassment resulting from the condition may be eliminated by routine surgical procedures.

25. A further condition encountered in plaintiff Rosenberg's specialization is menstrual bleeding which is abnormal because of its volume and frequency. While the condition is neither life threatening nor such as to interfere with essential function or cause severe pain, it may proceed to a point where the patient is unable to leave her house for several days every two weeks. In such circumstances, where the condition has not responded to other available forms of treatment and when hormone therapy cannot be used because of side effects, surgical removal of the bleeding organ is commonly recommended and performed.

26. Vaginal hysterectomy is a further surgical procedure designed to deal with a medical condition productive of little or no pain, nor any threat to life or essential function but which nonetheless is commonly performed where treatment with a pessary becomes excessively burdensome and interferes with normal sexual relations. In the absence of treatment or surgery the condition may be grossly unsightly and productive of emotional trauma.

27. Condyloma Accuminata or venereal warts, growths in and around the vulva, are similarly unsightly and productive of emotional trauma, although they produce, at most, irritation and itching and do not threaten life or the performance of normal sexual functions. Where such growths are of sufficient size as not to be controllable by drug therapy, surgical procedures are commonly carried out to relieve the patient of the undesirable symptoms.

28. With respect to each of the medical conditions referred to in paragraphs 20 through 27 above, plaintiff physicians are unable to perform and Medicaid patients, including plaintiff Jane Doe, are unable to benefit from the surgical procedures necessary to alleviate the conditions by reason of the recent amendments to New York's Social Services Law contained in Chapter 76. Since the surgical procedures may all be deferred without jeopardy to life or essential function or causing severe pain, defendants cannot certify such procedures for payment under the State Medicaid Program and in the absence of such payment plaintiffs are in no position to carry them out.

29. Moreover, the expressions "jeopardizing life or essential function" and "severe pain" have no commonly understood meaning in the medical profession and in numerous situations honest and reasonable physicians will differ as to their meaning and application. For this reason and since any classification in terms of the intensity of pain to an individual is a definition so subjective as to assure that similar cases will be treated differently, Chapter 76 will inevitably result in unequal treatment to Medicaid patients suffering from essentially identical medical complaints and deny them due process of law in violation of the Fifth and Fourteenth Amendments to the United States Constitution and the New York State Constitution.

30. So, too, the authority granted to defendant Commissioner of Health to permit certain otherwise deferrable surgery to be carried out on the basis of "medically indicated risk factors," without specification of the nature of the risk

7 7
referred to, is so vague and general as to violate due process and assure unequal treatment of similarly situated Medicaid patients. Illustrative of the vague parameters of the authority conferred on the defendant Commissioner in this respect is the manner in which he has exercised it. Thus, in regulations issued pursuant to this section, the Commissioner has arbitrarily and unconstitutionally permitted reimbursement under Medicaid for sterilization, by tubal ligation and vasectomy, and voluntary abortions -- both surgical procedures which may be deferred without threat to life, essential function or severe pain -- despite the fact that neither on the basis of medically indicated risk factors nor on any other medical basis, is there any reason for permitting such procedures to be reimbursed while denying reimbursement in the case of other types of deferrable surgery.

31. By reason of the foregoing, Chapter 76 of the Laws of New York, 1976, and defendants' acts pursuant thereto violate the Medicaid Act and regulations issued pursuant thereto since the statute and regulations issued pursuant thereto fail to provide for payments to qualified persons for medically necessary inpatient hospital care and physicians' services ordinarily provided by hospitals and doctors in New York State within the scope of the practice of medicine as defined by State law.

32. Chapter 76 and defendants acts pursuant thereto likewise violate the Medicaid Act and regulations issued pursuant thereto since they arbitrarily deny and reduce the amount, duration and scope of inpatient hospital care and physicians services solely because of the diagnosis, type of illness and condition.

33. Chapter 76 and defendants' acts pursuant thereto further violate the Supremacy Clause of the United States Constitution since they conflict with the laws of the United States on the same subject matter.

34. Chapter 76 and defendants' acts pursuant thereto further create classifications without rational basis, constitute invidious discrimination, and deny Medicaid patients equal protection of the laws to which they are entitled under the Fifth and Fourteenth Amendments to the United States Constitution and the New York State Constitution.

35. Chapter 76 and defendants' regulations issued pursuant thereto further are of such generality, subjectivity and vagueness as to deny plaintiffs their rights to due process of law guaranteed to them by the Fifth and Fourteenth Amendments to the United States Constitution and the New York State Constitution.

36. Plaintiffs have no adequate remedy at law.

37. Plaintiffs have suffered and will continue to suffer irreparable injury unless they are awarded the relief requested herein.

SECOND CAUSE OF ACTION

38. Plaintiffs repeat and reallege each and every allegation contained in Paragraphs 1-37 hereof with the same force and effect as if fully set forth herein.

39. Section 3 of Chapter 76 amends §365-a of the New York Social Services Law by requiring that a second opinion be obtained as a condition of reimbursement under Medicaid with respect to any deferrable surgery not excepted by defendant Commissioner of Health on the basis of "medically indicated risk factors."

40. The requirement of such a second opinion, which under the statute may not even have to be the opinion of another doctor, violates the right of privacy of patients such as plaintiff Doe, and the right of physicians such as plaintiffs Koff and Rosenberg to practice their profession in accordance with their best medical judgment, in violation of the First, Ninth and Fourteenth Amendments to the United States Constitution.

THIRD CAUSE OF ACTION

41. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1-40 hereof with the same force and effect as if fully set forth herein.

42. Section 3 of Chapter 76 amends §365-a of the New York Social Services Law by adding a new subdivision 5, which limits medical assistance to a maximum of one patient day of pre-operative hospital care unless the Commissioner of Health excepts "specific surgical procedures" from this limitation.

43. Section 4 of Chapter 76 amends §365-a of the New York Social Services Law to provide that the Commissioner of Health may promulgate standards limiting the duration of inpatient care, which can be "in no case greater than twenty days per spell of illness." The Commissioner of Health may make exceptions if a further identifiable period "is required for particular patients to preserve life or to prevent substantial risks of continuing disability."

44. The limitation of reimbursement to a maximum of one day of pre-operative care and a maximum of twenty days of hospital care is in conflict with federal law and regulations. Section 1902(a)(19) of the Social Security Act requires

that a state plan must provide care and services "in a manner consistent with simplicity of administration and the best interests of the recipients." Federal regulations further require that the "items must be sufficient in amount, duration and scope to reasonably achieve their purpose" and services may not be arbitrarily denied or reduced in "amount, duration or scope... solely because of the diagnosis, type of illness or condition." 45 C.F.R. 249.10(a)(5)(i). Moreover, as alleged in paragraph 17 above, the same Federal regulations provide that inpatient hospital services are "those items and services ordinarily furnished by the hospital," and physicians' services are "those services provided, within the scope of practice of his profession as defined by State law."

45. In addition to abrogating the principle that the same scope of care be provided to Medicaid patients as to non-Medicaid patients, the limitations on the duration of reimbursable hospital stays do not serve either administrative simplicity or the best interests of patients, in violation of the statute and regulations quoted in paragraph 44 hereof. The exceptions to the limitations fails to reconcile administrative simplicity with the best interests of patients in that the exception to the one day limitation on pre-operative care only takes account of the type of case and fails to take account of differing individual needs. Plaintiff physicians encounter many situations in which individual patients, due to factors other than the type of surgical procedure, require more than one day of pre-operative care. The exception to the twenty day maximum limitation on reimbursement for hospital care during

any one spell of illness, by contrast, takes account of individual patients' needs, but only if necessary "to preserve life or to prevent substantial risks of continuing disability." Plaintiff physicians encounter numerous situations in which longer periods of hospital care are medically required although earlier discharge from the hospital will not threaten life or create a risk of disability.

46. The limitations on the reimbursable durations of pre-operative and total inpatient care in Chapter 76 thus violate the Social Security Act and to the Supremacy Clause embodied in Article VI of the United States Constitution.

47. The standards by which the exceptions to the inpatient care limitations are to be promulgated create irrebuttable presumptions without a compelling state interest, which are violative of the Due Process clauses of the Fifth and Fourteenth Amendments to the United States Constitution.

WHEREFORE, plaintiffs pray

(a) that this Court declare and adjudge that Sections 3 and 4 of Chapter 76 of the Laws of New York, 1976 and defendants' regulations issued pursuant thereto are unlawful and unconstitutional;

(b) that this Court preliminarily and permanently enjoin defendants and their successors, agents, servants, employees and attorneys from implementing, enforcing or attempting to enforce Chapter 76 of the Laws of New York, 1976 and the regulations issued pursuant thereto so long as the State of New York continues to participate in the Federal Medicaid Program; and

(c) that plaintiffs be awarded such other and further relief as to this Court may seem just and proper.

Dated: New York, New York
August , 1976

LeBOEUF, LAMB, LEIBY & MacRAE

By _____
Charles P. Sifton
(A Member)

Attorneys for Plaintiffs
140 Broadway
New York, New York 10022
(212) 269-1100

and

J. Richard Burns, Esq.
General Counsel
The Medical Society of the
State of New York
420 Lakeville Road
Lake Success, New York 11040

United States District Court

FOR THE

EASTERN DISTRICT OF NEW YORK

CIVIL ACTION FILE NO. 76 CIV. 1443
(GCP)

THE MEDICAL SOCIETY OF THE STATE
OF NEW YORK, a New York not-for-
profit corporation, MORTON M. KOFF,
M.D., MILTON ROSENBERG, M.D., JANE
DOE and RAYMOND ORTEGA, an infant
seventeen years of age suing by
his friend and parent, RICARDA
ORTEGA,

Plaintiffs

v.

PHILIP TOIA, as Commissioner of the
Department of Social Services of
the State of New York and ROBERT
P. WHALEN, M.D., as Commissioner
of the Department of Health of
the State of New York,

Defendants

SUPPLEMENTAL
SUMMONS

To the above named Defendant s :

You are hereby summoned and required to serve upon

LeBoeuf, Lamb, Leiby & MacRae

plaintiff's attorney , whose address is:

140 Broadway, New York, New York 10005

an answer to the ^{first amended} complaint which is herewith served upon you, within the ^{time remaining to answer:} ~~XXXXXXXXXXXXXXXXXXXX~~
the original complaint heretofore filed and served herein.
~~XX~~ If you fail to do so, judgment by default will be
taken against you for the relief demanded in the complaint.

S/ Lewis Angel
Clerk of Court.
S/ Marilyn Glenn
Deputy Clerk.

Date: 8-20-76

[Seal of Court]

NOTE:—This summons is issued pursuant to Rule 4 of the Federal Rules of Civil Procedure.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----- x
THE MEDICAL SOCIETY OF THE STATE OF :
NEW YORK, a New York not-for-profit :
corporation, MORTON M. KOFF, M.D., :
MILTON ROSENBERG, M.D., JANE DOE, and :
RAYMOND ORTEGA, a seventeen year old :
infant suing by his parent and :
next friend, RICARDA ORTEGA, :

Plaintiffs, :

- against -

PHILIP TOIA, as Commissioner of the : 76 CIV. 1443
Department of Social Services of the : (PRATT)
State of New York and ROBERT P. WHALEN, :
M.D., as Commissioner of the Department :
of Health of the State of New York, :

Defendants. :

FIRST AMENDED
COMPLAINT FOR
DECLARATORY JUDGMENT
AND INJUNCTIVE RELIEF

----- x
Plaintiffs, by their attorneys, LeBoeuf, Lamb,
Leiby & MacRae, for their complaint herein, respectfully allege
as follows:

PRELIMINARY STATEMENT

1. This is an action for preliminary and permanent
injunctive relief and for a declaratory judgment brought by The
Medical Society of the State of New York (the "Medical Soci-
ety"), Morton M. Koff and Milton Rosenberg, doctors of medicine
licensed to practice under the laws of New York, Jane Doe and
Raymond Ortega, who are patients entitled to medical assistance
under the joint Federal and State program for medical assist-
ance provided for under Title XIX of the Social Security Act,
42 U.S.C. §1396 et seq. ("Medicaid").

2. On March 30, 1976, the Governor of the State of New York signed into law Chapter 76 of the Laws of New York, 1976 ("Chapter 76"), substantially, unconstitutionally and illegally limiting the authority of defendant Philip Toia, as Commissioner of Social Services of the State of New York, to certify for payment requests for reimbursement for various types of surgical procedures and inpatient hospital care under Medicaid, pursuant to regulations to be issued by defendant Robert P. Whalen, M.D., as Commissioner of Health.

3. Section 3 of the new law eliminates all benefits for surgery for Medicaid patients other than (1) benefits "for emergency or urgent surgery for the alleviation of severe pain, for immediate diagnosis or treatment of conditions which threaten disability or death if not promptly diagnosed or treated"; (2) benefits for certain other surgical procedures "as established by the state commissioner of health on the basis of medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with surgical intervention"; and (3) other "deferrable" surgical procedures based on the likelihood, established by two written opinions, that deferral of the surgical procedures for six months or more "may jeopardize life or essential function, or cause severe pain". In addition, the new law limits pre-operative hospital care for reimbursable surgical procedures to a maximum of one day, except with regard to specific surgical procedures identified by the State Commissioner of Health as requiring a longer period of pre-operative hospital care, and limits benefits for hospital care to a maximum of twenty

days, unless it is determined that a longer period of hospital care is required in particular cases in accordance with procedures and criteria established by the Commissioner of Health "to preserve life or to prevent substantial risks of continuing disability."

4. Acting pursuant to Chapter 76, defendants Toia and Whalen have violated and continue to violate Title XIX of the Social Security Act and Federal regulations issued pursuant thereto, the Supremacy Clause embodied in Article VI of the United States Constitution, the First, Fifth, Ninth and Fourteenth amendments to the United States Constitution and the Constitution of the State of New York.

5. The effect of defendants' conduct pursuant to Chapter 76 has been to deny to certain Medicaid patients, including plaintiffs Jane Doe and Raymond Ortega, certain deferrable surgical procedures which would otherwise be furnished to them by licensed practitioners of medicine within the scope of their practice as defined by State law and to interfere with the practice of medicine of doctors, including plaintiffs Rosenberg and Koff and other members of plaintiff Medical Society, who would otherwise recommend and carry out such deferrable surgical procedures with respect to their Medicaid patients, thus jeopardizing their continued ability to provide high quality health care to the low income and indigent residents of New York State.

FIRST CAUSE OF ACTION

Plaintiffs

6. Plaintiff Medical Society is a New York not-for-profit corporation having its principal place of business at 420 Lakeville Road, Lake Success, New York and is organized for the purpose of providing administrative assistance to its 28,000 physician members and of enhancing "the delivery of medical care of high quality to all people in the most economical manner; [and] to promote the betterment of community health". Bylaws, Article I.

7. Plaintiff Milton Rosenberg is a Doctor of Medicine, duly licensed to practice under the laws of the State of New York and a member of plaintiff Medical Society. Plaintiff Rosenberg specializes in obstetrics and gynecology and maintains an office for his practice at 485 New North Ocean Avenue in Patchogue, Long Island and treats substantial numbers of patients covered by Medicaid as well as patients not covered by that program.

8. Plaintiff Morton M. Koff is a Doctor of Medicine, duly licensed to practice under the laws of the State of New York and a member of plaintiff Medical Society. Plaintiff Koff specializes in the practice of family medicine and maintains an office for his practice at 801 E. Park Avenue in Long Beach, Long Island and treats substantial numbers of patients covered by Medicaid as well as patients not covered by that program.

9. Plaintiff Jane Doe is a low income resident of Long Island, New York who is receiving financial assistance under the Aid for Families with Dependant Children provisions

of the Social Security Act, 42 U.S.C. §601 et seq. and who is qualified by reason of her financial status for medical assistance under the Medicaid Program. She is a middle-aged mother of several children who has a long-standing relationship as the patient of a physician member of the staff of Brookhaven Memorial Hospital, Patchogue, Long Island. Her chief symptom is dysfunctional bleeding from an enlarged uterus which is approximately twice its normal size, which bleeding occurs in unusual volume on approximately a bi-monthly basis. Her physician recommends that she undergo a dilatation and curettage, a surgical procedure normally performed in these circumstances, and which, prior to enactment of Chapter 76, would have been covered by Medicaid. However, because her condition does not at present threaten life or disability if not promptly diagnosed or treated and because surgery may be deferred for six months without threat to life or essential function or causing severe pain, the operation is not covered under Chapter 76 and she is presently unable to obtain relief from her physician. If the injunction requested herein is not granted, plaintiff Jane Doe will be forced to continue to suffer the abnormal bleeding, together with the physical discomfort and emotional trauma caused by her condition, indefinitely, to her irreparable injury.

10. Plaintiff Raymond Ortega is a seventeen year old resident of New York City living with his mother and next friend, Ricarda Ortega, by whom he brings this action. Plaintiff Ortega is receiving financial assistance under the Aid for Families with Dependant Children provisions of the Social

Security Act, 42 U.S.C. §601 et seq. and is qualified for medical assistance under the Medicaid program.

11. As a child of seven plaintiff Ortega suffered 35% burns of the 2nd and 3rd degree of his face, neck and chest for which he was treated at the Albert Einstein Burn Center in New York where he received multiple skin grafts for his condition.

12. In recent weeks plaintiff Ortega and his mother have applied to Mount Sinai Hospital in New York City for a condition diagnosed as severe burn scar of the right side of the face causing an ectropion of the right lower eyelid and a significant contracture at the angle of the mouth. Plaintiff Ortega's condition presently causes him severe social embarrassment and emotional trauma and, unless corrected by surgery, will in time result in recurrent conjunctivitis. As a result, plaintiff Ortega has been recommended for surgery in the immediate future. However, because plaintiff Ortega's condition does not threaten death or disability unless performed promptly and will not cause severe pain or threaten life or essential function if deferred for six months or more, the surgery cannot be paid for at this time under Medicaid and has had to be deferred, to plaintiff Ortega's irreparable injury.

Defendants

13. Defendant Philip L. Toia is, and at all times relevant to this proceeding was the Commissioner of Social Services of the State of New York. The New York State Department of Social Services, under defendant Toia's direction, has and threatens to limit certification for payment for surgical

procedures pursuant to Chapter 76 to otherwise qualified Medicaid patients.

14. Defendant Robert P. Whalen, M.D., is and at all times relevant to this proceeding was, the Commissioner of Health of the State of New York. The Department of Health, under defendant Whalen's direction, has acted pursuant to Chapter 76 to issue regulations purporting to limit surgical procedures for which defendant Toia may certify payment under Medicaid.

JURISDICTION AND VENUE

15. This action arises under the Medicaid Act, 42 U.S.C. §1396 et seq. and the regulations promulgated thereunder, 42 U.S.C. §1983, Article VI of the United States Constitution and the First, Fifth, Ninth and Fourteenth Amendments thereto, the New York State Constitution, the New York Social Services Law and Public Health Law and the regulations promulgated pursuant thereto.

16. Jurisdiction is vested in this Court under 28 U.S.C. §§1331, 1343, 2201 and 2202 and principles of pendent jurisdiction. The amount in controversy exceeds the sum of \$10,000 exclusive of interest and costs.

17. Venue lies in this District pursuant to 28 U.S.C. §1391.

STATEMENT OF FACTS

18. The Federal government currently provides monies to states for the provision of medical assistance to qualified low income and indigent persons pursuant to a joint Federal-State program known as Medicaid governed by Title XIX of the Social

Security Act, 42 U.S.C. §1396 et seq., and the regulations promulgated thereunder.

19. The Medicaid Act requires that any state which accepts monies from the Federal government pursuant to the Medicaid Program have in effect a state plan providing that qualified low income and indigent persons be entitled to payment for inpatient hospital services and physicians' services furnished by licensed practitioners within the scope of their practice as defined by State law. 42 U.S.C §1396d(a)(1) and (5). Federal regulations pursuant thereto provide that the state plan must cover "inpatient hospital services" defined as "those items and services ordinarily furnished by the hospital for the care and treatment of inpatients provided under the direction of a physician" as well as "physicians' services" defined as "those services provided, within the scope of his practice as defined by State law, by or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy." 45 C.F.R. §249.10(b)(1) and (b)(5). Federal regulations further provide that:

"The State may not arbitrarily deny or reduce the amount, duration or scope of such services for an otherwise eligible individual solely because of the diagnosis, type of illness or condition." 45 C.F.R. §249.10(a)(5)(i).

20. New York State has, since 1966, had in effect a State Medicaid Program purporting to comply with all Federal requirements and authorizing and directing the acceptance of Federal funds under the Federal Medicaid Program and their disbursement to qualified persons for medical assistance certified as proper for payment by the Department of Social Services. New York Social Services Law, Title 11. Included in

such program has been provision for certification and payment for surgical procedures and physicians services "necessary to prevent, diagnose, correct or cure conditions ... that cause acute suffering, endanger life, result in illness or infirmity, interfere with ..[the patient's] capacity for normal activity, or threaten some significant handicap...". Social Services Law §365-a.

21. On March 30, 1976, the Governor of New York State signed into law Chapter 76 amending Section 365-a of the Social Services Law, significantly limiting the authority of defendant Toia to certify for payment certain surgical procedures theretofore paid under the State program. Thus Section 3 of the new law, after directing that "medical assistance shall not include any in-patient surgical procedures or any care, services or supplies related to such surgery other than those authorized by this subdivision," eliminated all deferrable surgery other than (1) surgery that, based on two written opinions, may not be deferred for six months or more without jeopardizing life or essential function or causing severe pain and (2) certain other surgical procedures designated by the Commissioner of Health on the basis of "medically indicated risk factors" and medically necessary surgery where delay would substantially increase the medical risk associated with surgical intervention.

22. Pursuant to such authority, defendant Whalen has promulgated regulations eliminating reimbursement under Medicaid for deferrable surgery, except for five specified types of surgical procedures, unless such surgery cannot be deferred for

six months or more without jeopardizing life or essential function or causing severe pain, and limiting hospital care according to criteria established by the Commissioner of Health as required by Chapter 76.

23. Plaintiffs Rosenberg, Koff and numerous others of the members of plaintiff Medical Society have, on a regular basis as part of the ordinary practice of their profession and within the scope of practice of that profession as defined by State law, occasion to recommend and perform medically necessary surgery for patients qualified for Medicaid, both on an inpatient and outpatient basis, in numerous situations not excepted by defendant Whalen's regulations in which two doctors can not be expected to certify that the surgery could not be deferred for six months or more without jeopardizing life or essential function or causing severe pain. Included among such situations are the following:

24. On numerous occasions plaintiff Koff has had and expects to have in the future qualified Medicaid patients suffering from hemorrhoids, a rupturing of veins in the anal canal, causing swelling and, frequently, minor bleeding. This disorder usually results in itching and minor physical discomfort and may cause embarrassing staining of the patient's clothing in the vicinity of the anus. The patient's condition can be corrected by inpatient surgery. However, deferral of such surgery for six months or more would in most cases in no sense jeopardize life or essential function of the patient or cause him severe pain.

25. Dr. Koff also on a regular basis has occasion to be consulted and expects in the future to be consulted by

qualified Medicaid patients suffering from benign tumors of the skin which present unsightly distortions of their facial features or other members. These complaints as well do not, in the usual case, cause more than minor discomfort. Nor do they jeopardize the patient's life or essential function although they frequently result in social embarrassment and social ostracism and, on occasion, difficulties in obtaining employment and social company. The elimination of these grossly unsightly tumors may, however, be accomplished by modern surgery on either an inpatient or outpatient basis.

26. Plaintiff physicians also as part of their authorized practice of medicine under New York State law have continuous occasion to diagnose and treat lipoma or other benign tumors of the vulva suffered by Medicaid patients, a disorder which does not ordinarily cause pain except during sexual intercourse performed in a manner which creates pressure on the tumor. Life and essential function are not jeopardized since sexual intercourse can still be performed and reproduction can still occur, and pain can be avoided and is not severe. Nevertheless, surgical procedures are commonly performed to alleviate the condition because of the serious emotional trauma which frequently results from the difficulties it creates in sexual relations.

27. A not uncommon medical condition witnessed by plaintiff Rosenberg in his specialization of gynecology and obstetrics is cystocele or dropping of the bladder. Symptoms of this condition, resulting from a relaxation of ligaments

retaining urine in the bladder, include loss of urine, consequent odor and staining following minor muscle spasms associated with sneezing, coughing or laughing. The condition is in no sense life threatening, typically causes no pain, nor does it jeopardize any essential function. However, the frequently resulting emotional trauma, social and economic dislocations and embarrassment resulting from the condition may be eliminated by routine surgical procedures.

28. A further condition encountered in plaintiff Rosenberg's specialization is menstrual bleeding which is abnormal because of its volume and frequency. While the condition is neither life threatening nor such as to interfere with essential function or cause severe pain, it may proceed to a point where the patient is unable to leave her house for several days every two weeks. In such circumstances, where the condition has not responded to other available forms of treatment and when hormone therapy cannot be used because of side effects, surgical removal of the bleeding organ is commonly recommended and performed.

29. Vaginal hysterectomy is a further surgical procedure designed to deal with a medical condition productive of little or no pain, nor any threat to life or essential function but which nonetheless is commonly performed where treatment with a pessary becomes excessively burdensome and interferes with normal sexual relations. In the absence of treatment or surgery the condition may be grossly unsightly and productive of emotional trauma.

30. Condyloma Accuminata or venereal warts, growths in and around the vulva, are similarly unsightly and productive

of emotional trauma, although they produce, at most, irritation and itching and do not threaten life or the performance of normal sexual functions. Where such growths are of sufficient size as not to be controllable by drug therapy, surgical procedures are commonly carried out to relieve the patient of the undesirable symptoms.

31. With respect to each of the medical conditions referred to in paragraphs 23 through 30 above, plaintiff physicians are unable to perform and Medicaid patients, including plaintiffs Jane Doe and Raymond Ortega, are unable to benefit from the surgical procedures necessary to alleviate the conditions by reason of the recent amendments to New York's Social Services Law contained in Chapter 76. Since the surgical procedures may all be deferred without jeopardy to life or essential function or causing severe pain, defendants cannot certify such procedures for payment under the State Medicaid Program and in the absence of such payment plaintiffs are in no position to carry them out.

32. Moreover, the expressions "jeopardizing essential function" and "severe pain" have no commonly understood meaning in the medical profession and in numerous situations honest and reasonable physicians will differ as to their meaning and application. For this reason and since any classification in terms of the intensity of pain to an individual is by definition so subjective as to assure that similar cases will be treated differently, Chapter 76 will inevitably result in unequal treatment to Medicaid patients suffering from essentially identical medical complaints in direct violation of 45 C.F.R. 249.10(a)(6) and (7), and will deny them due

process of law in violation of the Fifth and Fourteenth Amendments to the United States Constitution and the New York State Constitution.

33. So, too, the authority granted to defendant Commissioner of Health to permit certain otherwise deferrable surgery to be carried out on the basis of "medically indicated risk factors," without specification of the nature of the risk referred to, is so vague and general as to violate due process and assure unequal treatment of similarly situated Medicaid patients. Illustrative of the vague parameters of the authority conferred on the defendant Commissioner in this respect is the manner in which he has exercised it. Thus, in regulations issued pursuant to this section, the Commissioner has arbitrarily and unconstitutionally permitted reimbursement under Medicaid for sterilization, by tubal ligation and vasectomy, and voluntary abortions -- both surgical procedures which may be in many cases deferred without threat to life, essential function or severe pain -- despite the fact that neither on the basis of medically indicated risk factors nor on any other medical basis, is there any reason for permitting such procedures to be reimbursed while denying reimbursement in the case of other types of deferrable surgery.

34. By reason of the foregoing, Chapter 76 of the Laws of New York, 1976, and defendants' acts pursuant thereto violate the Medicaid Act and regulations issued pursuant thereto since the statute and regulations issued pursuant thereto fail to provide for payments to qualified persons for medically necessary inpatient hospital care and physicians'

services ordinarily provided by hospitals and doctors in New York State within the scope of the practice of medicine as defined by State law.

35. Chapter 76 and defendants acts pursuant thereto likewise violate the Medicaid Act and regulations issued pursuant thereto since they arbitrarily deny and reduce the amount, duration and scope of inpatient hospital care and physicians services solely because of the diagnosis, type of illness and condition.

36. Chapter 76 and defendants' acts pursuant thereto further violate the Supremacy Clause of the United States Constitution since they conflict with the laws of the United States on the same subject matter.

37. Chapter 76 and defendants' acts pursuant thereto further create classifications without rational basis, constitute invidious discrimination, and deny Medicaid patients equal protection of the laws to which they are entitled under the Fifth and Fourteenth Amendments to the United States Constitution and the New York State Constitution.

38. Chapter 76 and defendants' regulations issued pursuant thereto further are of such generality, subjectivity and vagueness as to deny plaintiffs their rights to due process of law guaranteed to them by the Fifth and Fourteenth Amendments to the United States Constitution and the New York State Constitution.

39. Plaintiffs have no adequate remedy at law.

40. Plaintiffs have suffered and will continue to suffer irreparable injury unless they are awarded the relief requested herein.

SECOND CAUSE OF ACTION

41. Plaintiffs repeat and reallege each and every allegation contained in Paragraphs 1-40 hereof with the same force and effect as if fully set forth herein.

42. Section 3 of Chapter 76 amends §365-a of the New York Social Services Law by requiring that a second opinion be obtained as a condition of reimbursement under Medicaid with respect to any deferrable surgery not excepted by defendant Commissioner of Health on the basis of "medically indicated risk factors."

43. The requirement of such a second opinion, which under the statute may not even have to be the opinion of another doctor, violates the right of privacy of patients such as plaintiff Doe, and the right of physicians such as plaintiffs Koff and Rosenberg to practice their profession in accordance with their best medical judgment, in violation of the First, Ninth and Fourteenth Amendments to the United States Constitution.

THIRD CAUSE OF ACTION

44. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1-43 hereof with the same force and effect as if fully set forth herein.

45. Section 3 of Chapter 76 amends §365-a of the New York Social Services Law by adding a new subdivision 5, which limits medical assistance to a maximum of one patient day of pre-operative hospital care unless the Commissioner of Health excepts "specific surgical procedures" from this limitation.

46. Section 4 of Chapter 76 amends §365-a of the New York Social Services Law to provide that the Commissioner of

Health may promulgate standards limiting the duration of inpatient care, which can be "in no case greater than twenty days per spell of illness." The Commissioner of Health may make exceptions if a further identifiable period "is required for particular patients to preserve life or to prevent substantial risks of continuing disability."

47. The limitation of reimbursement to a maximum of one day of pre-operative care and a maximum of twenty days of hospital care is in conflict with federal law and regulations. Section 1902(a)(19) of the Social Security Act requires that a state plan must provide care and services "in a manner consistent with simplicity of administration and the best interests of the recipients." Federal regulations further require that the "items must be sufficient in amount, duration and scope to reasonably achieve their purpose" and services may not be arbitrarily denied or reduced in "amount, duration or scope... solely because of the diagnosis, type of illness or condition." 45 C.F.R. 249.10(a)(5)(i). Moreover, as alleged in paragraph 17 above, the same Federal regulations provide that inpatient hospital services are "those items and services ordinarily furnished by the hospital," and physicians' services are "those services provided, within the scope of practice of his profession as defined by State law."

48. In addition to abrogating the principle that the same scope of care be provided to Medicaid patients as to non-Medicaid patients, the limitations on the duration of reimbursable hospital stays do not serve either administrative simplicity or the best interests of patients, in violation of

the statute and regulations quoted in paragraph 44 hereof. The exceptions to the limitations fails to reconcile administrative simplicity with the best interests of patients in that the exception to the one day limitation on pre-operative care only takes account of the type of case and fails to take account of differing individual needs. Plaintiff physicians encounter many situations in which individual patients, due to factors other than the type of surgical procedure, require more than one day of pre-operative care. The exception to the twenty day maximum limitation on reimbursement for hospital care during any one spell of illness, by contrast, takes account of individual patients' needs, but only if necessary "to preserve life or to prevent substantial risks of continuing disability." Plaintiff physicians encounter numerous situations in which longer periods of hospital care are medically required although earlier discharge from the hospital will not threaten life or create a risk of disability.

49. The limitations on the reimbursable durations of pre-operative and total inpatient care in Chapter 76 thus violate the Social Security Act and to the Supremacy Clause embodied in Article VI of the United States Constitution.

50. The standards by which the exceptions to the inpatient care limitations are to be promulgated create irrebuttable presumptions without a compelling state interest, which are violative of the Due Process clauses of the Fifth and Fourteenth Amendments to the United States Constitution.

WHEREFORE, plaintiffs pray

(a) that this Court declare and adjudge that Sections 3 and 4 of Chapter 76 of the Laws of New York, 1976

and defendants' regulations issued pursuant thereto are unlawful and unconstitutional;

(b) that this Court preliminarily and permanently enjoin defendants and their successors, agents, servants, employees and attorneys from implementing, enforcing or attempting to enforce Chapter 76 of the Laws of New York, 1976 and the regulations issued pursuant thereto so long as the State of New York continues to participate in the Federal Medicaid Program; and

(c) that plaintiffs be awarded such other and further relief as to this Court may seem just and proper.

Dated: New York, New York
August , 1976

LeBOEUF, LAMB, LEIBY & MacRAE

By S/ CHARLES P. SIFTON
Charles P. Sifton
(A Member)

Attorneys for Plaintiffs
140 Broadway
New York, New York 10022
(212) 269-1100

and

J. Richard Burns, Esq.
General Counsel
The Medical Society of the
State of New York
420 Lakeville Road
Lake Success, New York 11040

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X File
Medical Society, et al :
Plaintiffs, :
-against- : ANSWER
TOIA, et ano : 76 Civ. 1443
Defendants. : G.C.P.
-----X

Defendants, by their attorney, LOUIS J. LEFKOWITZ,
Attorney General of the State of New York answer the complaint
as follows:

1. Admit the characterization of the relief
requested in paragraph "1" Deny knowledge or information
sufficient to form a belief as to the truth or accuracy of
other allegations of this paragraph.

2. Deny the allegations of paragraph "2" in so
far as it alleges that chapter 76 is for any reason unlawful,
and refer to Chapter 76 in its entirety for a true statement of
its contents.

3. With respect to paragraph "3", refer to the full
text of the appropriate statute for a true statement of its
contents.

4. Deny the allegations of paragraphs "4", "5", "31",
"32", "33", "34", "35", "36", "37", "38", "39", "40", "49", and
"50".

5. Deny knowledge or information sufficient to form
a belief as to the truth or accuracy of the allegations of
paragraphs "6", "7", "8", "9", "10", "11", "12", "23".

6. Admit the allegations of the first sentence of paragraph "13". Deny that the defendant Toia "threatens" to limit certification pursuant to Chapter 76, and allege that defendant Toia exercises his duties and responsibilities in accordance with the law.

7. Admit the allegations of the first sentence of paragraph "14". Admit the allegations of the second sentence of this paragraph "14" except refer to the appropriate published statute and regulations in their entirety for a true statement of their contents.

8. Deny that this case is authorized or lies under 42 USC § 1396 et seq. 42 USC §1983, or any portion of the United States Constitution, New York State Constitution, or state law and regulations, as alleged in paragraph "15" or otherwise.

9. Deny that this court has jurisdiction as alleged in paragraph "16" or otherwise.

10. Deny that venue is proper as alleged in paragraph "17" or otherwise.

11. With respect to paragraphs "18", "19", "20", "21", "22", "42", "45", "46" refer to the full text of the appropriate statutes and regulations in their entirety for a true statement of their contents.

12. Deny knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations of paragraphs "24", "25", "26", "27", "28", "29", "30", and allege that analysis of every medical case turns on the facts of each case.

13. Deny the allegations of the first sentence of paragraph "47". With respect to the remaining allegations of this paragraph, refer to the appropriate relevant statutes and regulations in their entirety for a true statement of their contents.

14. Deny the allegations of the first and second sentence of paragraph "48". Deny knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations of the third and fifth sentences. In response to the fourth sentence, refer to the full text of the appropriate relevant statutes and regulation for a true statement of their contents.

15. With respect to paragraph "41" of the complaint, reallege defendants answer to paragraphs "1" through "40" of the complaint.

16. With respect to paragraph "44" of the complaint, reallege defendants answers to paragraph "1" through "43" of the complaint.

AS AND FOR A FIRST SEPARATE
AND COMPLETE DEFENSE

Defendants have violated no constitutional right of plaintiffs.

AS AND FOR A SECOND SEPARATE
AND COMPLETE DEFENSE

Defendants have violated no statutory right of plaintiffs.

AS AND FOR A THIRD SEPARATE
AND COMPLETE DEFENSE

Plaintiffs have no standing to sue.

AS AND FOR A FOURTH SEPARATE
AND COMPLETE DEFENSE

The complaint raises no case or controversy.

AS AND FOR A FIFTH SEPARATE
AND COMPLETE DEFENSE

The complaint fails to state a claim on which relief
can be granted.

AS AND FOR A SIXTH SEPARATE
AND COMPLETE DEFENSE

This Court has no subject matter jurisdiction.

AS AND FOR A SEVENTH SEPARATE
AND COMPLETE DEFENSE

The complaint must be dismissed for failure to exhaust
available state and administrative remedies.

WHEREFORE, defendants demand judgment dismissing the
complaint, costs and attorneys fees.

LOUIS J. LEFKOWITZ,
Attorney General of the
State of New York
Attorney for Defendant
By

RALPH McMURRY
Assistant Attorney General
Office & P.O. Address
Two World Trade Center
New York, New York 10047

CORRECTIONS IN TESTIMONY
(changes are underscored)

DEPOSITION OF DOUGLAS EVANS:

<u>page</u>	<u>line</u>	<u>IS</u>	<u>SHOULD BE</u>
7	6	<u>20</u> percent	<u>10</u> percent
8	19	Dr. <u>Warten</u>	Dr. <u>Wharton</u>
9	6	"	"
	12	"	"
	24	"	"
10	19-20	<u>are not</u> by	<u>which is</u> by
14	12	I <u>can</u>	I <u>can't</u>
15	17	Dr. <u>Wartens</u>	Dr. <u>Wharton</u>

DEPOSITION OF ROBERT SEINFELD:

4	18	Patchough	Patchogue
5	8	Diplomat_	Diplomate_
	16	I intership	I interned
	23	And <u>you</u> you	And <u>do</u> you
6	23	surgery <u>from</u> a	surgery <u>for</u> a
	24	currently suffering <u>from</u> ?	currently suffering?
7	8	threatened <u>to a</u> death	threatened <u>by</u> death
	18	"Medical_ indicated	" <u>Medically</u> indicated
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DEPOSITION OF ROBERT SEINFELD (cont.)

<u>page</u>	<u>line</u>	<u>IS</u>	<u>SHOULD BE</u>
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	14	Rosenburg	Rosenberg
	20	"	"
	24	"	"
9	2	"	"
	3	requires	require
	5	cyst	cysts
	9	<u>Or</u> any of	<u>Are</u> any of
	10	Commission	Comissioner
	11	Medical indicated	Medically indicated
	13	cystocele	cystocoele
10	5	conditions _ for a	conditions ? for a
	5	cystocele	cystocoele
	8	it is asymptomatic,	it is <u>sometimes</u> asymptomatic,
	8	, <u>they cannot cause</u> <u>any</u>	, <u>not causing</u> any
	10	cystocele	cystocoele
	12	carry	carries
	16	<u>That</u>	<u>In that</u>
11	14	malignant <u>which</u> it	malignant <u>in</u> it
	19	groups_ women	group, women
12	16	might <u>not</u> be	might be

DEPOSITION OF ROBERT SEINFELD (cont.)

<u>page</u>	<u>line</u>	<u>IS</u>	<u>SHOULD BE</u>
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	19	"	"
	20	, 100 percent <u>of</u>	_ 100 percent _
	22	<u>Warten</u>	<u>Wharton</u>
	23	"	"
	25	doctor?	doctor_
20	4	<u>dis</u> functional	<u>dys</u> functional
	11	<u>dilation</u>	<u>dilatation</u>
21	5	have <u>the</u> difficult	have <u>a</u> difficult
	6	own <u>practice</u> in	own <u>patients</u> in
	10	patient_	patients_

DEPOSITION OF EDGAR ALTCHER:

1	17	<u>ALCHEK</u>	<u>ALTCHER</u>
5	4	"	"
	12	<u>Alchek</u>	<u>Altcher</u>
6	24	Title <u>19</u>	Title XIX
9	20	he does_	he does <u>not</u> .
10	18	I think <u>his</u>	I think <u>this</u> .
12	12	a <u>patient</u>	a <u>paying</u> patient

DEPOSITION OF EDGAR ALTCHER (cont.)

<u>page</u>	<u>line</u>	<u>IS</u>	<u>SHOULD BE</u>
	4	<u>I absolutely</u>	<u>Yes, I absolutely</u>
	19	condition <u>essentially</u>	condition <u>eventually</u>
13	14	Medical <u>indicated</u>	Medically <u>indicated</u>
	21	"	"
	22	the <u>term</u> of	the <u>type</u> of
14	5	<u>patient a day</u>	<u>day</u>
	7	one <u>patient</u> day	one <u>day</u>
	15	chief <u>actor</u>	chief <u>factor</u>
	15	<u>a patient here.</u>	<u>the patient himself.</u>
	18	conditions;	conditions
	19	<u>for example he may</u> <u>require</u>	<u>that require</u>
	20	<u>It may be</u>	<u>For example, it may be</u>
16	5	, <u>did</u> you	, <u>do</u> you
	23	<u>Probably the</u> work-up.	<u>Pre-operative</u> work-up.
20	15	memorandum <u>7689</u>	memorandum 76-89

DEPOSITION OF MORTON M. KOFF:

4	16	<u>family practice</u>	<u>Family Practice</u>
	22	State <u>Associations,</u>	State <u>Medical Association,</u>
5	7	Title <u>19</u>	Title <u>XIX</u>
6	14	<u>medical</u> <u>indicated</u> <u>risk factors?</u>	<u>"medically indicated</u> <u>risk factors"?</u>
	16	, <u>medically</u>	, <u>"medically</u>

DEPOSITION OF MORTON M. KOFF (cont.)

<u>page</u>	<u>line</u>	<u>IS</u>	<u>SHOULD BE</u>
	17	factors_in	factors" in
7	8	<u>to consult a surgeon</u> <u>or a surgeon of</u>	<u>or to consult a surgeon</u> <u>of</u>
8	6	<u>leproma</u>	<u>lipoma</u>
	8	<u>Leproma</u>	<u>Lipoma</u>
	14	<u>of leproma</u>	<u>for lipoma</u>
10	13	<u>avocation</u>	<u>application</u>
	16	<u>Dr. Warten</u>	<u>Dr. Wharton</u>
	20	number <u>7689?</u>	number 76-89?
11	9	<u>Warten's</u>	<u>Wharton's</u>
	10	"	"
	14	<u>Warten</u>	<u>Wharton</u>

1
2 UNITED STATES DISTRICT COURT
3 EASTERN DISTRICT OF NEW YORK
4 -----x

5 THE MEDICAL SOCIETY OF THE STATE OF :
6 NEW YORK, a New York not-for-profit :
7 corporation, MORTON M. KOFF, M.D., :
8 MILTON ROSENBERG, M.D., JANE DOE, and :
9 RAYMOND ORTEGA, a seventeen year old :
10 infant, by his next friend and parent, :
11 RICARDA ORTEGA, :

12 Plaintiffs, : Index No. 76 Civ.144B
13 (Pratt)

14 -against- :

15 PHILIP TOIA, as Commissioner of the :
16 Department of Social Services of the :
17 State of New York and ROBERT P. WHALEN, :
18 M.D., as Commissioner of the Department :
19 of Health of the State of New York, :

20 Defendants. :
21 -----x

22 DEPOSITION of DR. EDGAR ALCHEK

23 a witness for the Plaintiff, held on
24 August 26, 1976 at the Eastern District
25 of New York, 225 Cadman Plaza East, at or
about 9:50 A.M. before a Notary Public of
the State of New York.

EASTERN DISTRICT COURT REPORTERS

174

Appearances:

MES^{RS}. LEBOEUF, LAMB, LEIBY & MACRAE
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140 Broadway
New York, N.Y. 10005

BY: CHARLES P. SIFTON, ESQ.
Of Counsel

LOUIS LEFKOWITZ, ESQ.
Attorney General of the State of New York
Attorney for Defendants
2 World Trade Center
New York, N.Y.

BY: RALPH MCMURRY, ESQ.
Of Counsel

IT IS HEREBY STIPULATED AND AGREED, by and between the attorneys for the respective parties herein, that the sealing, filing and certification of the within deposition be waived; that such deposition may be signed and sworn to before any officer authorized to administer an oath, with the same force and effect as if signed and sworn to before the officer before whom said deposition was taken.

IT IS FURTHER STIPULATED AND AGREED that all objections, except as to form, are reserved to the time of trial.

IT IS FURTHER STIPULATED AND AGREED that counsel for the witnesses appearing herein shall be furnished with a copy of the within deposition without cost.

1
2 MR. MC MURRY: I want to make one statement
3 for the record. This is your witness with respect to
4 Mr. Ortega?

5 MR. SIFTON: Yes.

6 MR. MC MURRY: I just want to say for the
7 record the State takes the position that Mr. Ortega
8 is not a proper party to this insofar as the purpose
9 of the preliminary injunction is concerned.

10 I myself never saw the supplemental amended
11 complaint until Monday afternoon or Tuesday afternoon.
12 I do not recall exactly whether it was the 23rd or
13 24th of August.

14 The papers in this case on the preliminary
15 injunction were to have been submitted by Monday.
16 Obviously, insofar as Mr. Ortega is concerned, the
17 defendants do not have proper time in which to look
18 into that matter.

19 MR. SIFTON: I would merely state that the Judge
20 has given the State until Tuesday to submit additional
21 material on this point and that the amendment to the
22 complaint was served on the state last Friday and that
23 the answering papers from the State did answer or
24 attempt to answer the allegations with regard to
25 Mr. Ortega.

MR. MC MURRY: Nevertheless, cross-examination is today, not Tuesday.

D R . E D G A R A L C H E K, having been called as a witness on behalf of the Plaintiff, after having been first duly sworn by a Notary Public, was examined and testified as follows:

EXAMINATION

BY MR. SIPTON:

Q Would you state your name and address for the record, Dr. Alchek?

A Edgar Alchek. My office address is 102 East 78th St., New York City.

Q What is your profession?

A I am a physician, practicing -- specialist practicing in plastic and reconstructive surgery.

Q Are you also licensed to practice that profession by the State of New York?

A Yes, I am.

Q When were you so licensed?

A 1965.

Q do you have an association with any hospital in New York City?

A Yes, I do.

Q What hospital is that and what is your

1
2 position?

3 A I am associated with Mt. Sinai Hospital. I'm
4 on the attending staff of Mt. Sinai.

5 Q Are you a member of any professional organization?

6 A Yes, I am. I am a Diplomate of the American
7 Board of Plastic Surgeons, Member of the American
8 Association of Plastic and Reconstructive Surgeons. Fellow
9 of the American College of Surgeons. Member of the American
10 Medical Association. Fellow of the New York Academy of
11 Medicine. I am a Member of the New York Society of Plastic
12 and Reconstructive Surgeons.

13 Q What is your education in the field of medicine?

14 A Do I go back to medical school?

15 Q Yes.

16 A I graduated New York Medical College in 1965.
17 I interned in Beth Israel Hospital in 1965 to 1966.

18 Residency in General Surgery from 1966 through 1969. I had
19 a residency in plastic surgery from 1969 to 1972.

20 Q Do you hold any teaching positions in your field?

21 A Yes. I am on the faculty of Mt. Sinai's School
22 of Medicine.

23 Q Are you familiar with the program known as
24 Medicaid provided under Title 19 of the Social Security Act?

25 A Yes, I am.

1
2 Q Do you have occasion at Mt. Sinai Hospital to
3 perform surgery with respect to indigent and low-income
4 patients covered by Medicaid?

5 A Yes.

6 Q Are you familiar with the recent enactment of
7 Chapter 76 of the laws of the State of New York, and
8 specifically with the provision of the statute stating the
9 types of surgery which may be reimbursed under Medicaid?

10 A Yes.

11 Q Now, are you familiar with the medical condition
12 of Raymond Ortega, one of the plaintiffs in this proceeding?

13 A Yes, I am.

14 Q Would you state under what circumstances
15 Mr. Ortega came to Mt. Sinai Hospital when you became
16 familiar with the case?

17 A Hewas initially -- I saw him at the plastic
18 surgery clinic at Mt. Sinai Hospital. I saw him personally
19 in preparation of this case.

20 Q Are you familiar at all with the financial
21 circumstances of Mr. Ortega and his family?

22 A Apparently, he is an indigent individual.

23 Q Had your department recommended that Ray
24 Ortega obtain surgery for a medical condition from which he
25 is currently suffering?

1
2 A Yes.

3 Q Would you describe for the record Mr. Ortega's
4 condition and the medical history which resulted in his
5 condition?

6 A Mr. Ortega is a 17-year-old male who, when he
7 was 7 years old, apparently peered into the engine of a taxi
8 when the hood was up and someone threw a match into the engine.

9 The engine exploded in his face resulting in
10 35 per cent, second and third-degree burns to his face, arms,
11 hands, chest, abdomen.

12 He was initially treated at Jacoby Hospital
13 where he had a skin graft and since he has undergone some
14 reconstructive surgery for correction of contractures and
15 deformities of his arms.

16 He underwent a surgical procedure for a
17 correction of a deformity of his right eyelid. He has since
18 continued to have deformities of his eyelid and deformities
19 of his face, particularly about the mouth.

20 He was seen in the plastic surgery clinic for
21 the complaints, particularly regarding his right lower eye-
22 lid and his mouth. It was the opinion of the people who
23 examined him that reconstructive surgery was indicated to
24 improve his facial appearance.

25 Q Is the condition which he suffers from, with

1
2 regard to his right lower eyelid, does that have a technical
3 term in medicine?

4 A Yes, it's ectropion.

5 Q And would you describe physically how ectropion
6 can develop from the burn scars which Mr. Ortega suffered
7 from?

8 A Burnscarring of the cheek pulls down the
9 lower eyelid causing the eyelid to be pulled down, exposing
10 more of the eye, the eyeball than one would like. Such a
11 condition in such a case, the eyelids do not adequately
12 protect the eyeball and the patient can go on to develop
13 severe problems.

14 Q Now, in your opinion is Mr. Ortega threatened
15 with death or disability unless this condition is immediately
16 treated?

17 A No.

18 Q So that he does not qualify in your opinion for
19 surgery on an urgent or emergency basis?

20 A Yes, sir, he does.

21 Q In your opinion, is the condition from which Mr. Ortega
22 suffers one of the five listed by the Commissioner of Health
23 as exempting him from the limits of Chapter 76 based on
24 "medically indicated risk factors"?

25 A No.

1
2 Q In your opinion, will deferral of surgery on
3 Mr. Ortega for six months threaten his life or essential
4 functions or cause him severe pain?

5 A In terms of severe pain?

6 Q I'll repeat the question; in your opinion
7 will deferral of surgery on Mr. Ortega for six months
8 threaten his life, first of all?

9 A No, it wouldn't threaten his life.

10 Q Or threaten essential functions?

11 A No.

12 Q Or cause him severe pain?

13 A No.

14 Q And what is the basis for your Department's
15 recommendation of surgery at this time?

16 A He has a severe disfigurement of his face.
17 On the basis of that it merits reconstructive surgery.

18 I think his patient who has sought medical
19 attention for this problem, he's not solicited, the patient
20 came in voluntarily because of this problem. This merits
21 surgical attention.

22 We can help this individual. He was -- he
23 was certainly severely distressed by his appearance to the
24 point that he did come to a surgeon asking for surgery to
25 correct his condition. People do not voluntarily seek surgery

1
2 unless it's absolutely necessary.

3 This individual certainly would like his
4 appearance improved and it's incumbent upon us, as physicians,
5 to improve his appearance as best as possible and as
6 expeditiously as possible.

7 Mr. Ortega is emotionally disturbed by his
8 problem. He is very conscious about his appearance in public.
9 He cannot go to the beach. If you see him I think you can
10 understand why.

11 I think that the mere fact he has come to us
12 and at this particular point in time, means we should
13 treat him and treat him as expeditiously as possible.

14
15 (continued next page)
16
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25

1
2 Q Would you treat a patient that came to you with
3 this condition as expeditiously as possible?

4 A I absolutely think if a patient comes for
5 surgery he's coming for a reason. In Mr. Ortega's case I
6 don't know what exactly the reason was that he came at this
7 time. Maybe he has a girl friend and he may for some reason
8 be more self-conscious at this time than he was six months
9 ago.

10 In any case he did come to us now. If we for
11 any reason postpone surgery unduly, Mr. Ortega might decide
12 that he doesn't want the surgery. Not that he doesn't need
13 it, but he may be afraid.

14 I don't think it's fair to him. as an
15 individual just because he is indigent to be deprived of
16 surgery. A patient who has some form of insurance would be
17 operated upon more expeditiously.

18 Q In your opinion, will surgery to correct
19 Mr. Ortega's condition essentially necessitate surgery at
20 some time?

21 A Yes.

22 Q Directing your attention briefly to the phrase
23 "severe pain," as it is used in the statutes and regulations,
24 are you, based on your experience and education as a Doctor
25 of Medicine, able to give us a definition of that phrase?

1
2 A No. I don't know what severe pain is. It's
3 a subjective term. There is no way whatsoever of measuring
4 pain and certainly no way of measuring its severity.

5 As I say, it's perfectly subjective. It's
6 a relative term and it's not like measuring blood pressure or
7 pulse or respiration. We have no way of measuring severe
8 pain.

9 What is pain, severe pain to one individual may be
10 mild to another.

11 Q Directing your attention to that portion of
12 Chapter 76 which authorizes the Commissioner of Health to
13 exempt certain surgery procedures from the limitations of
14 that Chapter 76, on the basis of medical indicated risk
15 factors, can you tell us as a doctor or as a reader of plain
16 English what meaning that phrase has?

17 A I don't understand it at all.

18 Q Directing your attention to the regulation
19 issued by the Commissioner of Health, pursuant to his
20 authority to exempt certain surgery procedures, "on the basis
21 of medical indicated risk factors," for abortions,
22 vasectomies, are you aware of any difference in the term of
23 medical risk factors between vasectomies and abortions and
24 other surgery procedures which are not exempt from the
25 Chapter 76?

1
2 A No.

3 Q Turning to those provisions of the State which
4 state medical assistance is limited to a maximum of one
5 patient a day of pre-operative care, except with respect to
6 specific surgical procedures, which the State Commissioner of
7 Health has identified as requiring more than one patient-day
8 of pre-operative care, would you state whether in your
9 opinion the duration of appropriate pre-operative care can
10 be determined solely on the basis of the type of operation
11 for which the patient is scheduled?

12 A Not at all.

13 Q What other factors must be considered in every
14 case?

15 A The chief actor is a patient here. We're
16 operating upon a patient and we don't tailor the patient to
17 fit the operation. We suit the operation to the patient and
18 the patient himself may have underlying medical conditions;
19 for example, he may require that he be in the hospital for
20 more than one day. It may be necessary to perform certain
21 tests and to determine his fitness for surgery.

22 It may be necessary to prepare him medically
23 for surgery. You cannot predict, you cannot legislate the
24 length of a stay of any particular patient that may require
25 surgery.

Q Do you have any estimate of the number of patients, Medicaid patients that Mt. Sinai performed surgery on over any period of time?

A I don't know, but it is a large number.

MR. SIFTON: Do you have any cross-examination?

MR. MC MURRY: Yes. Just a minute.

EXAMINATION

BY MR. MC MURRY:

Q Doctor, is it your testimony that reconstructive surgery was recommended for Mr. Ortega?

A I'm sorry, did I what?

Q Is it your testimony that reconstructive surgery was recommended for Mr. Ortega?

A Yes, sir.

Q When was that recommendation made?

A When he was seen in the clinic. I don't know exactly when.

Q Approximately when?

A I don't know. I think between the past month, but I'm not sure --

Q Has he had surgery in the past?

A Yes, he has.

Q Who paid for the surgery in the past?

A As far as I know, it was Medicaid.

1 Q Has he ever been referred to the Crippled
2 Child's Program?

3 A I don't know.

4 Q In your opinion, did you consider vision an
5 essential function?

6 A Yes.

7 Q In your opinion, if the reconstructive surgery
8 is not performed would the contracture cause damage to the
9 eye?

10 A Yes.

11 Q Have you read the amended complaint in this
12 case?

13 A I don't know what that is.

14 Q You have not?

15 A I don't know what it is.

16 Q Could these tests be performed on an out-
17 patient basis to limit the pre-operative status to one day?

18 A No.

19 MR. SIFTON: Mr. McMurry, you said test?

20 MR. MC MURRY: Yes.

21 MR. SIFTON: You mean surgery or test?

22 MR. MC MURRY: Probably the work-up.

23 THE WITNESS: Pre-operative work-up?

24 Q Yes.
25

1
2 Q Prior to that time did you state that or did you
3 not state that Mr. Ortega was not suffering from severe pain?

4 A I didn't state it. I wasn't asked the question.

5 Q Is it possible that his condition would cause
6 damage to the eye if not operated on?

7 A Eventually.

8 Q What do you mean by eventually?

9 A Perhaps years.

10 MR. MC MURRY: I have no further questions.

11 EXAMINATION

12 BY MR. SIFTON:

13 Q Dr. Alchek, in looking through Chapter 76, did
14 you see any exemption in that statute for the Crippled
15 Children's Program?

16 A No.

17 Q Does Mt. Sinai have a hospital utilization
18 review program?

19 A Yes.

20 Q And if Mr. Ortega were admitted to Mt. Sinai
21 would his admission be reviewed in terms of medical necessity
22 under the program?

23 A Yes.

24 MR. SIFTON: No further questions.
25

1
2 A You want to rephrase the question?

3 Q The question is is it possible that the pre-
4 operative work-up could be done on an out-patient basis to
5 limit the --

6 A The pre-operative work could be done on an
7 out-patient basis.

8 Q Was any application ever made to the Crippled
9 Children's Program, to your knowledge?

10 A I don't know.

11 Q Are you familiar with the Crippled Children's
12 Program?

13 A No.

14 Q Is it possible that pre-operative testing would
15 limit the stay to one day prior to surgery?

16 A No. The patient would have to be admitted the
17 day before surgery in any case, no matter what pre-operative
18 tests were done before he was admitted. He does have to
19 receive -- he has to be adequately medicated before the
20 surgery and we do not like to undertake this surgery having
21 the patient come in immediately before the operation.

22 Q Was it your testimony that Mr. Ortega was not
23 suffering severe pain, early on in your testimony --

24 A I was asked what I felt the term severe pain
25 meant.

EXAMINATION

BY MR. MC MURRY:

Q Who is the utilization review program coordinator at the hospital?

A I don't know.

Q Did you consult anyone in the utilization review committee or any representative of the utilization review committee regarding coverability of this case?

A That's automatically done when admission is requested through the clinic.

Q But you did not personally do that?

A No.

Q Do you know who did it?

A The resident who applied for the patient's admission to the hospital.

Q Do you know that for a fact are you just assuming that is the case?

A It's the only way the patient could be admitted to the hospital.

Q Did anyone ever tell you this would not be covered?

A Yes. The doctor who is responsible for the patient.

Q Who is?

A Dr. Kisner.

Q Was any appeal taken, to your knowledge?

A I don't know.

MR. MC MURRY: Thank you.

EXAMINATION

BY MR. SIPTON:

Q Where is Dr. Kisner this morning?

A Dr. Kisner is operating this morning.

Q On a case which you would have otherwise been assisting on; is that right?

A Exactly.

EXAMINATION

BY MR. MC MURRY:

Q Have you seen the hospital memorandum 7689, are you familiar with it?

MR. SIPTON: Could you show it to him if you want to ask him questions, please?

Q Are you familiar with that?

A No.

Q Have you ever seen it before?

A No. I've seen parts of it.

Q And what parts have you seen?

A I thought I seen -- wait. I thought I had seen this before, no. I guess I haven't seen it, no.

1
2 MR. MC MURRY: I ask this be marked as
3 Defendant's Exhibit 1 for identification.

4 (So marked.)

5 Q Is it your testimony there will be damage to the
6 eyelid in this case?

7 A Ultimately.

8 Q There would be damage to the eye?

9 A Could be or would be?

10 Q Could be.

11 A Could be, yes.

12 Q Is it possible that such damage might be
13 progressive in nature?

14 MR. SIFTON: Mr. McMurry, I object to
15 speculation of possibilities. Anything is possible.
16 This is a doctor and you can ask his opinion.

17 MR. MC MURRY: He was speculating in response
18 to some of your questions.

19 MR. SIFTON: I beg to differ. I asked questions
20 as to his opinion.

21 MR. MC MURRY: Admissibility and relevancy is
22 something the Judge will decide.

23 MR. SIFTON: I have noted my objection.

24 MR. MC MURRY: Would you like to have the
25 question read back?

THE WITNESS: Yes.

(Whereupon, the last question was read back
by the Court Reporter.)

A Yes.

MR. MC MURRY: I have no further questions.

EXAMINATION

BY MR. SIFTON:

Q Dr. Alchek, this operation will have to be
paid for by the State, in any event; is that correct?

A Yes.

Q It is your testimony it should be performed now
and you would perform it on a paying patient now?

A A paying patient or if he had some other form
of insurance.

MR. SIFTON: Thank you.

MR. MURRAY: Thank you.

DR. EDGAR ALCHEK

Subscribed and sworn to

before me this day of

1976.

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
THE MEDICAL SOCIETY OF THE STATE OF :
NEW YORK, a New York not-for-profit :
corporation, MORTON M. KOFF, M.D., :
MILTON ROSENBER, M.D., JANE DOE, and :
RAYMOND ORTEGA, a seventeen year old :
infant, by his next friend and parent, :
RICARDA ORTEGA, :

Plaintiffs, :

-against-

: Index No. 76 Civ. 1443
(Pratt)

PHILIP TOIA, as Commissioner of the :
Department of Social Services of the :
State of New York and ROBERT P. WHALEN, :
M.D., as Commissioner of the Department :
of Health of the State of New York, :

Defendants. :

-----x
DEPOSITION of DR. ROBERT SEINFELD

a witness for the Plaintiff, held on
August 26, 1976 at the Eastern District
of New York, 225 Cadman Plaza East, at or
about 10:10 A.M. before a Notary Public of
the State of New York.

EASTERN DISTRICT COURT REPORTERS

Appearances:

MESSRS. LEBORUF, LAMB, LEIBY & MACRAE
Attorneys for Plaintiffs
140 Broadway
New York, N.Y. 10005

BY: CHARLES P. CIFTON, ESQ.
Of Counsel

LOUIS LEFKOWITZ, ESQ.
Attorney General of the State of New York
Attorney for Defendants
2 World Trade Center
New York, N.Y.

BY: RALPH MCMURRY, ESQ.
Of Counsel

1
2 IT IS HEREBY STIPULATED AND AGREED, by and
3 between the attorneys for the respective parties herein,
4 that the sealing, filing and certification of the within
5 deposition be waived, that such deposition may be signed
6 and sworn to before any officer authorized to administer
7 an oath, with the same force and effect as if signed and
8 sworn to before the officer before whom said deposition
9 was taken.

10 IT IS FURTHER STIPULATED AND AGREED that all
11 objections, except as to form, are reserved to the time
12 of trial.

13 IT IS FURTHER STIPULATED AND AGREED that
14 counsel for the witnesses appearing herein shall be furnished
15 with a copy of the within deposition without cost.
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1 DR. ROBERT SEINFELD, having been called as
2 a witness on behalf of the plaintiff, having been
3 first duly sworn by a Notary Public of the State of
4 New York, was examined and testified as follows:

5 DIRECT EXAMINATION

6 BY MR. SIFTON:

7 Q Would you state your profession for the record?

8 A I'm a physician practicing obstetrics and
9 gynecology.

10 Q Are you licensed to practice by the State of
11 New York?

12 A Yes, I am.

13 Q When were you licensed?

14 A 1952.

15 Q What is your area of specialization?

16 A Obstetrics and gynecology.

17 Q Where do you practice your profession?

18 A In Patchough, New York.

19 Q Are you associated with any hospitals in that
20 area?

21 A Yes, I am.

22 Q Would you state the hospital?

23 A Brookhaven Memorial Hospital.

24 Q And what is the nature of your association with
25 that hospital?

1
2 A I'm an attending physician in obstetrics and
3 gynecology.

4 Q Are you a member of any professional organiza-
5 tions?

6 A Yes. I am a member of the New York State
7 Medical Association, American Medical Association, I'm a
8 Diplomat of Obstetrics and Gynecology, a Fellow of the
9 American College of Surgeons. I am a Fellow of the College
10 of Obstetricians and Gynecologists.

11 I am Assistant Professor at the State University
12 in Stoneybrook.

13 Q Would you state your education in the field of
14 medicine?

15 A I'm a graduate of New York University, Bellevue
16 College of Medicine, 1952. I internship at Kings County
17 Hospital from 1953 to -- excuse me, from 1952 to 1953. I
18 had a residency in obstetrics and gynecology from 1955 to
19 1959.

20 Q Are you familiar with the so-called Medicaid
21 program provided by Title 19 of the Social Security Act?

22 A Yes, I am.

23 Q And you you have occasion to treat indigent
24 and low income patients covered by that program?

25 A Yes, I do.

1
2 Q Are you familiar with the recently enacted
3 Chapter 76 of the laws of New York, 1976, specifically with
4 respect to the limiting types of surgery that may be reim-
5 bursed under Medicaid?

6 A Yes.

7 Q Are you acquainted with a woman patient who
8 has been called Jane Doe in the complaint in this proceeding?

9 A Yes, I am.

10 Q Under what circumstances do you know her?

11 A I have taken care of this woman for the last
12 twelve years, gynecologically.

13 Q Did you deliver any of her children?

14 A I'm pretty sure I did. But that goes back a
15 ways.

16 Q Are you familiar with Jane Doe's financial
17 circumstances?

18 A Yes, I am.

19 Q And would you describe them briefly?

20 A To the best of my recollection she has been on
21 Medicaid since I've known her.

22 Q Have you recommended to Jane Doe that she
23 obtain surgery from a medical condition from which she is
24 currently suffering from?

25 A Yes, I have.

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2 Q And what was the basis for your recommendation?

3 A Well, she has a condition -- we call it a
4 dysfunctional bleeding. It's bleeding from the urinal tract
5 and she bleeds from the vagina area and from her uterus twice
6 a month rather than the usual monthly menstrual cycle.

7 Q And at the time of your recommendation was
8 Jane Doe threatened to a death or disability unless her
9 condition was immediately diagnosed or treated?

10 A No.

11 Q And so she did not qualify for surgery on an
12 urgent or emergency basis?

13 A No. Not at all. I think she fits into a
14 pattern that I see hundreds of times a year.

15 Q In your opinion, was the condition from which
16 she suffers one of the five listed in the regulations of
17 the Commissioner of Health as exempt from the limitations of
18 Chapter 76, based on, "Medical indicated risk factors."

19 A No.

20 Q At the time of your recommendation was it your
21 opinion that deferral of surgery on Jane Doe for six months
22 would threaten her life or essential function or cause her
23 severe pain?

24 A No.

25 Q Is the dilatage and curettage operation a

1
2 surgical procedure ordinarily furnished by hospitals in New
3 York for the care and treatment of patients in Jane Doe's
4 situation?

5 A Yes, it is.

6 Q Are the services of a doctor in a dilation and
7 curettage provided by doctors within the scope of their
8 practice the way New York defines it?

9 A Yes.

10 Q Do you know a Milton Rosenberg, one of the
11 plaintiffs in this case?

12 A Yes I am.

13 Q What is your connection with Dr. Rosenberg?

14 A Dr. Rosenberg and I are in a partnership in
15 the practice of obstetrics and gynecology.

16 Q Can you tell us why Dr. Rosenberg is not here
17 today?

18 A Unfortunately he suffered a coronary three
19 weeks ago and he's bedridden at the moment.

20 Q Have you read the affidavit of Dr. Rosenberg
21 which is filed in this case?

22 A Yes, I have.

23 Q And do you agree with the statements made by
24 Dr. Rosenberg with regard to the effect of Chapter 76?

25 A Yes, I do.

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2 Q In his affidavit, Dr. Rosenberg refers to a
3 number of medical conditions which in his opinion requires
4 surgery, specifically a cystocele, venereal warts and ovarian
5 cyst. I ask you first whether these are typical cases and
6 do they result in death or disability if not immediately
7 diagnosed or treated?

8 A Not immediately, no.

9 Q Or any of those conditions specifically covered
10 by the Commission of Health under Medicaid, on the basis of
11 medical indicated risk factors?

12 A No.

13 Q And with respect to those conditions, cystocele,
14 venereal warts and ovarian cysts, ordinarily would deferral
15 of surgery for six months or more cause severe pain, threaten
16 life or essential function?

17 A No.

18 Q And do hospitals in New York State nevertheless
19 ordinarily provide facilities for the performance of surgery
20 with respect to these conditions?

21 A Yes.

22 Q And is it within the scope of your practice
23 as a doctor of medicine to perform surgery with respect to
24 these conditions?

25 A Yes.

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2 Q Now, would you describe these conditions and
3 let the record show the basis for which you and other New
4 York doctors customarily recommend surgery with respect to
5 these conditions for a cystocele?

6 A Well, a cystocele is a relaxation of the
7 bladder. It is a protrusion or hernia of the bladder into
8 the vagina, it is asymptomatic, they cannot cause any problem
9 and we may not touch them under that condition.

10 However, at times a cystocele will cause severe
11 distress and continence. It will cause her to lose her
12 urine when she coughs, sneezes or laughs or carry a heavy
13 package, and under those conditions the woman usually comes
14 in herself for surgery. She requests some kind of correction
15 of this difficulty.

16 That kind of a situation we would do a surgical
17 procedure which would also place the bladder back where it
18 was originally and prevent her from having any further
19 distress.

20 Q Is it uncommon for you to see this condition in
21 Medicaid patients?

22 A No, it's quite common. It comes typically
23 after a woman has many children and this is typical of our
24 indigent population. So, we see many of them with this
25 complaint.

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2 Q Turning to the venereal warts, can you describe
3 that condition and the circumstances customarily for recommend-
4 ing surgery?

5 A Venereal warts are warts, a warty growth that
6 occurs on the external genitalia of females. It is a
7 venereally contracted disease.

8 If they are not tremendously big, if they are
9 not very large, we may be able to cure them chemically.
10 However, when they get to a certain size it becomes rather
11 difficult to cure them chemically and we resort to surgical
12 means to remove them.

13 Q Turning to ovarian cysts; are there circumstances
14 where the cysts are not malignant which it nevertheless
15 requires surgery?

16 A Yes.

17 Q And would you explain?

18 A I would guess that most ovarian cysts, particu-
19 larly in the younger age groups women in their twenties and
20 thirties, are not malignant. When they reach a certain size
21 we usually like to take them out. Rarely there are cysts
22 that will diminish after the menstrual period and disappear.
23 However, when they reach five or six centimeters in diameter
24 we begin to think of a surgical procedure to remove them.

25 There is always -- there is the danger of later

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2 on, if these cysts persist and get larger and larger, of
3 causing some kind of abdominal problem. They may twist on
4 themselves and require urgent emergency surgery at that time.
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6 (Continued on next page.)
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Seinfeld

BY MR. SIFTON:

rs/ss 3 Q You also perform surgery where it is not an
R4 4 emergency?

5 A Yes.

6 Q And why?

7 A Well, there's no way of being 100 percent
8 certain there is not a malignancy or at some future time the
9 cyst will become malignant. So, we prefer to get them out when
10 we see them.

11 Q Do you also perform surgery sometimes because it
12 is unsightly and for discomfort?

13 A Not unsightly, a cyst does not show. Unless
14 they are tremendous, then we have to take it out. We've taken
15 out a cyst that weighs 30 pounds. When a woman comes in and
16 looks like she's nine months pregnant, it might not be benign
17 but certainly they have to come out. They are uncomfortable
18 at times.

19 Q Directing your attention to the expression,
20 "essential function," and the phrase, "threaten life or
21 essential function;" what do they mean to you as a doctor?

22 A I really don't know what essential function means
23 in the context of that law as I read it.

24 Q Directing your attention to the phrase, "severe
25 pain," as it appears in the regulation; can you tell us if that

Seinfeld

has an accepted medical meaning?

A No. It was pointed out before that is something that is completely subjective.

Q Does your office currently accept new Medicaid patients?

A Only if they are a dire emergency referred to me by another physician that we know locally. Otherwise we've stopped taking Medicaid patients.

Q And why is that?

A Well, where -- with this '76 chapter in front of us, we're being bombed with the thought of paperwork. It means hiring more help. It means waiting. If I ask for a second opinion, which I really don't believe is needed to begin with, because it doesn't fit the categories that were present, if I decided to go and circumvent a procedure and ask for a second opinion, by the time I got it it would be another month and you have to get through the hospital to get the patient in.

It's just too much of a hassle. It's hamstringing our practice.

Q Does Brookhaven Memorial Hospital have a hospital utilization review program?

A Yes.

Q If Jane Doe were admitted, would her admission

1
2 be subject to review by the utilization program?

3 A Within 24 hours.

4 Q And would it determine her need for surgery, if
5 there was no medical necessity for surgery, she would be
6 discharged?

7 A Yes. I would have three days, as I recall, in
8 our utilization review law to get this patient out of the
9 hospital under those conditions.

10 MR. SIFTON: Your witness.

11 EXAMINATION

12 BY MR. MCMURRY:

13 Q You say Jane Doe has been your patient for
14 twelve years; is that what you're saying?

15 A Yes, that's correct.

16 Q How long has this condition existed in Jane
17 Doe?

18 A This bleeding has been going on for approximately
19 two months now.

20 Q What is the normal course of treatment that
21 you would follow in treating a case similar to Jane Doe's?

22 A I would do a curettage on this patient, on any
23 patient that had this.

24 Q I'm sorry?

25 A I would do a dilatation and curettage on any

4 1

2 patient of this type.

3 Q Is that solely a surgical procedure or is it
4 also performed for other purposes of diagnosis?

5 MR. SIFTON: Do you understand the question?

6 THE WITNESS: You're mixing it up. It is a
7 surgical procedure done for several reasons. It is
8 done for diagnosis, if diagnosis is uncertain. It is
9 also done to effect a cure hopefully.

10 Q Well, what other possible diagnosis or condition
11 which could cause this type of bleeding --

12 MR. SIFTON: I object to that question as to
13 possibilities. You can ask his opinion as to what
14 circumstances --

15 MR. MCMURRY: This is a deposition. Relevancy
16 and admissibility are not questions on a deposition.
17 The objection may or may not be --

18 MR. SIFTON: It's an improper question. It is
19 not relevant.

20 MR. MCMURRY: Please answer the question?

21 THE WITNESS: Would you please repeat the
22 question?

23 MR. MCMURRY: Read it back, please?

24 (Whereupon, the Court Reporter read back the
25 last question.)

Seinfeld

1
2 A Well, there are a number of hormonal reasons
3 that she might be bleeding, chemical reasons. Reasons
4 because of some disfunction of her ovarian hormonancy she may
5 have pollups or an overgrowth in the uterus. She could have
6 -- she could have had an abortion, a pregnancy. She could
7 have had a malignancy, any number of reasons. I could go on
8 and on, it is endless.

9 Q Was any request in the case of Jane Doe made of
10 a hospital for admission?

11 A No. I decided, I thought I understand this law
12 and that I --

13 Q Excuse me?

14 A I thought I understood the meaning of the law
15 and I told this patient I couldn't take care of her at this
16 point.

17 Q Was there a determination, to your knowledge,
18 by the utilization review committee of coverability?

19 A There wouldn't be any unless the patient were
20 admitted to the hospital.

21 Q Did you make any request for admission of
22 Jane Doe to the hospital?

23 A No, I didn't.

24 Q I'm going to show you Defendant's Exhibit 1;
25 have you seen that before?

2 A I don't recall.

3 Q You don't recall?

4 A I may have, but I honestly don't recall.

5 Q What diagnosis have you made now in the case of
6 Jane Doe?

7 A Preoperative diagnosis?

8 Q Yes?

9 A Disfunctional bleeding.

10 Q Have you completely ruled out pregnancy or
11 cancer?

12 MR. SIPTON: I object to that, unless it's
13 based in terms of his opinion as to what her diagnosis
14 is.

15 Q In your opinion?

16 A Yes, I would say so. By the nature and the
17 duration and the amount and the time of the month that she
18 bleeds, yes, I would say that my diagnosis would remain
19 disfunctional bleeding.

20 If you're saying ruling out, 100 percent of
21 nothing is 100 percent.

22 Q Have you read the affidavit of Dr. Warten?

23 A Yes, I did. Wait a minute. Is it Dr. Warten --
24 when you say doctor, was he a medical doctor or a Ph.D.--

25 Q He's a medical doctor?

7 1

2 A May I see this again for a moment? I read that,
3 but I would like to refresh my memory.

4 Q Certainly.

5 A Yes, I did read it.

6 Q Let me turn your attention to paragraph 31; do
7 you recall reading that?

8 A Yes.

9 (Short pause.)

10 MR. SIFTON: I've got some further questions if
11 you want to reserve?

12 MR. MCMURRY: Yes, go ahead.

13 EXAMINATION

14 BY MR. SIFTON:

15 Q Doctor, with regard to Defendant's Exhibit 1,
16 are you familiar with the form of document called, "State of
17 New York, Department of Health, Hospital Memorandum;" that is
18 have you seen other hospital memoranda of the State of New
19 York, Department of Health, is it customarily circulated to
20 individual physicians throughout the state?

21 A No. Not to my knowledge. I haven't seen that.

22 Q And the hospital memoranda, are they to your
23 knowledge circulated to hospitals?

24 A I don't know.

25 MR. SIFTON: Do you have any further questions?

EXAMINATION

BY MR. MCMURRY:

Q In your opinion, doctor, what hardship would it be on Jane Doe if this operation is not performed?

MR. SIFTON: When?

Q Now?

A Well, there are two things that really could bother her. Number one, this woman is walking around with pads constantly, bleeding every two weeks. It's very uncomfortable. If she keeps on bleeding she could become anemic. Then she is going to require medical care for something else.

Q How long would it normally take, if the condition were not operated upon, for her to become anemic?

A There is no set answer to that.

Q Is it your testimony that her condition is not causing her severe pain?

A That's correct. She has no pain.

Q Does it threaten her life or disable her if she is not immediately properly diagnosed? In other words, this is not an urgent matter; is that correct?

A Right.

MR. MCMURRY: I have no further questions.

(Continued next page.)

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EXAMINATION

3

BY MR. SIFTON:

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5

6

Q Doctor, is the dysfunctional bleeding, from which Jane Doe is suffering, a common occurrence in your practice?

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A Yes. It's probably the most common thing we have seen in our practice. I would guess any gynecologist that is practicing for a while must see hundreds of these a year.

11

12

Q Is dilation and curettage a commonly performed surgical procedure?

13

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15

16

A Yes. I would say if this persists, most gynecologists may watch it for a while and if it persists more than a month, they would want to take this patient and stop it if possible --

17

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21

Do you know of any reason why hundreds of doctors and hundreds of patients throughout the state may not be faced with exactly the same situation that you and Jane Doe are faced with at present because of the operation of this law -

22

23

MR. MCMURRY: Objection to the form of the question.

24

25

Q Would you answer the question?

A It's going to happen in all communities. It's

Seinfeld

happening in our community now. Patients are being turned away for a particular type of situation and for many other situations.

I have the difficult time enough now seeing my own practice in the office. Now, if I am going to be asked every couple of days to see other doctors' patients for a problem that is very obvious, and all the other men are certified gynecologists, they know what they are seeing, I haven't got time to see their patient for an opinion and at the same time I would rather not see these people. I haven't got the time to see new patients in my office.

Q And if you stop new patients, how many other gynecologists are there in Patchogue to see these people?

A There are only about six others in the area serving about 100,000 people or more.

Q I would imagine they are just as busy as you are?

A Just as busy.

MR. SIFTON: Thank you. No further questions.

MR. MCMURRY: Thank you.

(Witness excused.)

ROBERT SEINFELD

Sworn to before me this

_____ day of _____, 1976.

NOTARY PUBLIC

1
2 UNITED STATES DISTRICT COURT
3 EASTERN DISTRICT OF NEW YORK
4 -----x

5 THE MEDICAL SOCIETY OF THE STATE OF :
6 NEW YORK, a New York not-for-profit :
7 corporation, MORTON M. KOFF, M.D., :
8 MILTON ROSENBER, M.D., JANE DOE, and :
9 RAYMOND ORTEGA, a seventeen year old :
10 infant, by his next friend and parent :
11 RICARDA ORIEGA, :

12 Plaintiffs, :

13 -against- :

14 : Index No. 76 Civ. 1443
15 (Pratt)

16 PHILIP TOIA, as Commissioner of the :
17 Department of Social Services of the :
18 State of New York and ROBERT P. WHALEN, :
19 M.D., as Commissioner of the Department :
20 of Health of the State of New York, :

21 Defendants. :
22 -----x

23 DEPOSITION of DR. MORTON M. KOFF

24 a witness for the Plaintiff, held on
25 August 20, 1976 at the Eastern District
of New York, 225 Cadman Plaza East, at or
about 10:45 A.M. before a Notary Public of
the State of New York.

EASTERN DISTRICT COURT REPORTERS

1
2 Appearances:

3
4 MESSRS. LEBOEUF, LAMB, LEIBY & MACRAE
5 Attorneys for Plaintiffs
6 140 Broadway
New York, N.Y. 10005

7 BY: CHARLES P. SIFTON, ESQ.
8 Of Counsel

9 LOUIS LEFKOWITZ, ESQ.
10 Attorney General of the State of New York
11 Attorney for Defendants
2 World Trade Center
New York, N.Y.

12 BY: RALPH MCMURRY, ESQ.
13 Of Counsel
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R5

1 IT IS HEREBY STIPULATED AND AGREED, by and
2 between the attorneys for the respective parties
3 herein, that the sealing, filing and certification of
4 the within deposition be waived; that such deposition
5 may be signed and sworn to before any officer
6 authorized to administer an oath, with the same force
7 and effect as if signed and sworn to before the
8 officer before whom said deposition was taken.

9 IT IS FURTHER STIPULATED AND AGREED that all
10 objections, except as to form, are reserved to the
11 time of trial.

12 IT IS FURTHER STIPULATED AND AGREED that counsel
13 for the witnesses appearing herein shall be furnished
14 with a copy of the within deposition without cost.
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1 D R . M O R T O N K O F F , having been called as a
2 witness on behalf of the plaintiff, having been first
3 duly sworn by a Notary Public of the State of New York,
4 was examined and testified as follows:

5 EXAMINATION

6 BY MR. SIFTON:

7 Q Dr. Koff, are you one of the plaintiffs in this
8 action?

9 A Yes.

10 Q And what is your profession?

11 A I am a physician.

12 Q Are you licensed by the State of New York to
13 practice this profession?

14 A Yes.

15 Q And do you have an area in which you specialize?

16 A I specialize in a family practice.

17 Q And where do you practice your profession?

18 A At 801 East Park Avenue, Long Beach, New York.

19 Q Are you a member of any professional
20 organizations?

21 A Yes. The American Medical Association, New
22 York State Associations, Society of Medicine, Nassau County.
23 Society of the New York Cardiologist and American Academy of
24 Family Practitioners.

25 Q And would you state your educational background

1
2 in medicine?

3 A In medicine, I went to the University of
4 Cincinnati, College of Medicine. I did a years internship
5 at Queens General Hospital.

6 Q Are you familiar with the Medicaid program
7 provided by Title 19 of the Social Security Act?

8 A Yes.

9 Q And do you have occasion to treat indigent and
10 low-income patients covered by Medicaid?

11 A Yes.

12 Q What portion of your practice is represented by
13 Medicaid patients?

14 A Through Medicaid, 15 percent Medicaid and
15 Medicare, about 65, 70 percent.

16 Q Would you tell us the difference between
17 Medicaid and Medicare?

18 A Persons over 65 or persons who are disabled who
19 have been accepted by the federal government social security
20 and the Department of Medicare. This is an additional form
21 of insurance, straight Medicaid patients only have Medicaid.

22 Q Are you familiar with the recently enacted
23 Chapter 76 of the state laws of the State of New York, 1976?

24 A Yes.

25 Q In your affidavit you refer to a number of

1

2 medical conditions in which, in your opinion, require
3 surgery, which you believe would not be covered by Medicaid
4 as a result of this act. Specifically bleeding hemorrhoids,
5 umbilical hernia and joint cartilage. Let me ask you first
6 whether in a typical case, they would result in death or
7 disability if not promptly diagnosed or treated?

8

A They do not.

9

Q They would not qualify as emergencies or urgent
10 surgery under the state law?

11

A They would not.

12

Q Are any of those conditions among those
13 specified by the Commissioner of Health as covered by the
14 Medicaid plan on the basis of medical indicated risk factors?

15

A They are not.

16

Q Do you understand that phrase, medically
17 indicated risk factors in the context of that?

18

A No, that is a phrase physicians never use.

19

Q With respect to any of those conditions, would
20 deferral for six months in a typical case cause severe pain
21 or result in threatened death or jeopardize the life or
22 essential functions of a person?

23

A It would not.

24

Q Do hospitals in New York State nevertheless
25 ordinarily provide facilities for the performance of surgery

1
2 with respect to these conditions?

3 A They do.

4 Q Is it within the scope of your practice as a
5 licensed physician by the State of New York, to perform
6 surgery with respect to these conditions?

7 A No, I do not perform the surgery. I recommend
8 the patient to a surgeon to consult a surgeon or a surgeon of
9 their choice.

10 Q Would you describe these conditions and tell the
11 Court the basis upon which you and other doctors customarily
12 recommend surgery with respect to these conditions, starting
13 with bleeding hemorrhoids?

14 A Well, the bleeding hemorrhoid is a lacerated
15 vein. The name of the vein is a hemorrhoidal vein. It is
16 in fact a varicose vein as most lay people are familiar with
17 in other parts of the anatomy.

18 When the vein is lacerated, small amounts of
19 blood come out almost constantly.

20 Q And why is surgery recommended with regard to
21 the treatment of this condition, when is it recommended?

22 A The patient is often completely incapacitated by
23 it because of the staining of the clothing. Especially men
24 find it hard to cope with. They cannot get employment, they
25 cannot go swimming, it goes through the bathing suit and

1
2 eventually there is a chance of anemia which would require
3 expenditures of time, energy and money to treat that, because
4 hemorrhoids are oozing constantly.

5 Q Would you answer the question with regard to
6 leproma which I understand to be a disease affecting the
7 vagina?

8 A Leproma can occur and ordinarily we do not
9 recommend a surgery, it is not disfiguring, but we just feel
10 -- however, in the vulva, it could destroy a marriage because
11 it interferes with the sexual behavior preferred by the
12 married couple. If it would in fact interfere with the
13 maintenance of the marriage, especially then we would
14 recommend surgery of leproma.

15 Q And with regard to umbilical hernias?

16 A Umbilical hernias occur most commonly in black
17 people and by statistical facts, therefore it is common in
18 the area of poor people, sometimes they would spontaneously
19 close themselves as the child grows older. Sometimes they
20 will not. In a teenager it is a disturbing factor and causes
21 tremendous anguish, for instance when a girl will not wear
22 any midriff clothing and so on and in that case we recommend
23 surgical correction.

24 Q Joint cartilage surgery?

25 A Joint cartilage surgery is something we

1
2 especially find in young athletes. If left unattended it's
3 when determined statistically we find they will form an
4 incapacitating arthritis many years later, it does in fact
5 occur. We therefore, when we make such a diagnosis or even
6 a presumptive diagnosis, the patient is referred to an
7 orthopedic surgeon who in turn recommends surgery, usually.

8 Q How is chapter 76 affecting you right now in
9 your practice?

10 A Well, right now I cannot in my community get
11 any orthopedics for straight Medicaid patients under any
12 circumstances. My two general surgeons will not accept any
13 surgery that might be excluded by this new law, because they
14 "Refuse to do the paperwork."

15 I don't know what my urologist and other
16 surgical consultants will say. The ones I have spoken to so
17 far have absolutely refused. That means sending them to the
18 county hospital, which is three hours by public transportation.

19 So in fact what happens, because it's a
20 three hour trip by public transportation, the Medicaid patient
21 just does not get the surgery. They are denied.

22 Q Who pays for the transportation if it's not a
23 medical necessity for transportation --

24 A Even if they're referred to go to Brookhaven, the
25 transportation is paid for by the State of New York, by

1
2 Medicaid.

3 MR. SIFTON: Thank you.

4 EXAMINATION

5 BY MR. MCMURRY:

6 Q Dr. Koff, is Jane Doe your patient?

7 A No, she's not.

8 Q And is Mr. Ortega your patient?

9 A No, he is not.

10 Q Do you have any knowledge of those circumstances?

11 A Just what I heard in Court.

12 Q You have an affidavit which you submitted in
13 support of the avocation for a preliminary injunction. Does
14 that affidavit set forth your understanding of Chapter 76?

15 A It does.

16 Q Did you read the affidavit of Dr. Warten which
17 was submitted by the defendants?

18 A Yes.

19 Q And are you familiar with the State Department of
20 Health, hospital memorandum, number 7689?

21 A No, I'm not familiar with it.

22 Q It is Defendant's Exhibit 1?

23 A I may have seen it.

24 Q Have you seen that?

25 (Attorney handing witness document.)

A I don't think so. No, I don't think so, no.

Q My understanding is that you recommended surgery, but you did not perform the surgery; is that correct?

A That's correct.

MR. MCMURRY: I have no further questions.

EXAMINATION

BY MR. SIFTON:

Q Having read Dr. Warten's affidavit, do you know Dr. Warten's field of specialization?

A I don't remember.

Q Is it set forth at all in the affidavit?

A No, it is not.

Q Does it set forth whether Dr. Warten is presently practicing or not?

A It does not.

MR. SIFTON: Is that it?

MR. MCMURRY: Do you have any more witnesses?

MR. SIFTON: No.

MR. MCMURRY: I have one.

(Whereupon, this witness was concluded.)

MORTON KOFF

Sworn to before me this _____

day of _____, 1976.

NOTARY PUBLIC

1
2 UNITED STATES DISTRICT COURT
3 EASTERN DISTRICT OF NEW YORK
4 -----x

5 THE MEDICAL SOCIETY OF THE STATE OF :
6 NEW YORK, a New York not-for-profit :
7 corporation, MORTON M. KOFF, M.D., :
8 MILTON ROSENBERG, M.D., JANE DOE, :
and RAYMOND ORTEGA, a seventeen-year- :
old infant, by his next friend and :
parent, RICARDA ORTEGA, :

Index No.
76 Civ. 1443
(Pratt)

9 Plaintiffs, :

10 -against- :

11 PHILIP TOIA, as Commissioner of the :
12 Department of Social Services of the :
13 State of New York and ROBERT P. WHALEN, :
M.D., as Commissioner of the Department :
of Health of the State of New York, :

14 Defendants. :
15 -----x

16
17 DEPOSITION OF DOUGLAS EVANS, a witness
18 for the Plaintiff, held on August 26, 1976 at the
19 Eastern District of New York, 225 Cadman Plaza East,
20 at or about 11:00 o'clock A.M., before a Notary
21 Public of the State of New York
22

23 EASTERN DISTRICT COURT REPORTERS
24
25

Appearances:

MESSRS. LEBOEUF, LAMB, LEIBY & MACRAE
Attorneys for Plaintiffs
140 Broadway
New York, New York 10005

BY: CHARLES P. SIFTON, ESQ.
Of Counsel

LOUIS LEFKOWITZ, ESQ.
Attorney General of the State of New York
Attorney for Defendants
2 World Trade Center
New York, New York

BY: RALPH MC MURRY, ESQ.
Of Counsel

1
2 IT IS HEREBY STIPULATED AND AGREED, by and
3 between the attorneys for the respective parties
4 herein, that the sealing, filing and certification of
5 the within deposition be waived; that such deposition
6 may be signed and sworn to before any officer
7 authorized to administer an oath, with the same force
8 and effect as if signed and sworn to before the
9 officer before whom said deposition was taken.

10 IT IS FURTHER STIPULATED AND AGREED that all
11 objections, except as to form, are reserved to the
12 time of trial.

13 IT IS FURTHER STIPULATED AND AGREED that
14 counsel for the witnesses appearing herein shall be
15 furnished with a copy of the within deposition without
16 cost.
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25

rs/ss 1 D O U G L A S E V A N S , having been called as a witness
R6 2 on behalf of the defendant, having been first duly
3 sworn by a Notary Public of the State of New York,
4 was examined and testified as follows:

5 EXAMINATION

6 BY MR. MCMURRY:

7 Q Mr. Evans, what is your present employment?

8 A State of New York, Department of Social Service
9 Division of Medical Assistance.

10 Q How long have you been so employed, sir?

11 A Two and a half years.

12 Q Before that?

13 A I was administrative resident, Long Beach
14 Memorial Hospital. Prior to that I was employed as an
15 assistant administrator at the St. Anthony's Hospital,
16 Denver, of the technical services.

17 Prior to that time I was unit coordinator for
18 the Massachusetts General Hospital for Orthopedic Services.

19 Q What are your duties at the present time?

20 A I'm director of the utilization control for
21 the New York State Medicaid program.

22 Q And what are your duties in that capacity?

23 A My duties consist of establishing state
24 policies and procedures with regard to the utilization of
25 services, patient services under the New York State Medicaid

1
2 program.

3 Q In connection with your duties, are you
4 familiar with the so-called Medicaid program, generally in
5 Chapter 76 in this case?

6 A I am.

7 Q If you know, can you make any estimate as to
8 the amount of resources that are conserved on a per diem
9 basis, if you know, by Chapter 76?

10 A Our latest estimates indicate they are in the
11 neighborhood of \$1,7million a day that is involved in the
12 portion of Chapter 76 that relates to surgical care. One
13 day preoperative and 20 day limitation on stay.

14 Q What is the basis of your estimation that you
15 have just given us?

16 A The basis of our estimation are derived from
17 data and supplies or aggregated from hospital billing forms
18 in New York State over the last year.

19 MR. MCMURRY: I have no further questions.

20 EXAMINATION

21 BY MR. SIFTON:

22 Q Mr. Evans, are you a doctor?

23 A No, I am not.

24 Q With regard to your estimate of resources
25 conserved, have you taken into account the amount of money

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which will be expended upon obtaining second opinions?

A Yes, I have.

Q And how much will second opinions cost in each case?

A The initial fee for the physicians will cost \$40. Plus additional tests that the physician may order to confirm his diagnosis. We estimate a second opinion will in total cost be \$50.

Q And how much is your total figure for the amount of money that will be spent from second opinions?

A \$1.5-million.

Q For what period of time?

A Annually.

Q And your million dollar figure is for what period of time?

A Daily.

Q \$1-million resources conserved for Chapter 76?

A For that portion of 76, that relates to one day preoperative and a 20 day limit and surgical controls.

Q What portion of that \$1-million is attributable to the 20-day limitation on the total hospital care, what portion of that million dollars?

A You'll have to excuse me, I'm doing the statistics in my head.

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Q Your best estimate?

A Approximately 25 percent.

Q And what portion is represented by limiting the preoperative care to one day?

A Less than 20 percent.

Q You say you base this estimate -- would you estimate again the basis on which you have made this estimate?

A Hospitals, as part of their billing procedure, fill out a form, either the DSS-2140 or the 220-B. This lists the procedures performed, the length of stay, the surgery performed and the dollar charges being made against the Medicaid program.

Copies of these bills are submitted centrally to the state and put on a computer tape for analysis as to the length of stay, diagnosis, so forth.

It's on the basis of that information supplied by hospitals, we based our estimates.

Q And you have taken the total of these forms and you've eliminated a certain portion of them and said these would be eliminated if we only had second opinions; is that correct?

A Based on the additional studies that have been performed, we have taken surgical cases under the Medicaid program and based our estimates on the fact that if the

1
2 estimates of the national studies are correct, we will save
3 that amount of money.

4 In other words, it's a combination of factors.

5 Q Would you say again what that combination
6 factor is?

7 A We are able to arrive at a figure of the
8 number of surgical cases performed in New York State
9 annually. If you take that figure and you use the results of
10 the studies performed by Dr. McCarthy and others, there is a
11 general figure you can arrive at. You can arrive at what
12 we consider to be a number of unnecessary surgical cases
13 performed.

14 Q Do you have any basis for saying that the
15 limitation of unnecessary surgery, which Dr. McCarthy
16 projects, will not be achieved simply by the hospital
17 utilization review program presently in effect?

18 A The knowledge that I would have would be
19 second-hand, based on the affidavit that Dr. Warten submitted,
20 which outlines specifically unnecessary cases of surgery
21 which have been performed while the hospital utilization program
22 had been in existence.

23 Q Has this program detected these unnecessary
24 surgeries?

25 A Yes.

1

2

Q Is that right?

3

A It has not. It allowed them to be performed.

4

Q But you now know they exist?

5

A We now know they exist.

6

Q And Dr. Warten also says in his affidavit that

7

there has been a marked decrease in the number of unnecessary

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surgery as a result of the operation of the hospital

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utilization review board; isn't that right?

10

A I don't believe that is a correct statement.

11

Q I direct your attention to page 9 and 10 of

12

Dr. Warten's affidavit which states that the New York State

13

Hospital Utilization Review Program was announced November 5th

14

and implemented in January -- in March, 1974 and he says the

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following: "Before any follow-up action of any kind there

16

was a notable acceleration of discharges of long-stay patients

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from twelve hospitals in one of the first regions in which

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the system was implemented." Could you explain your last

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answer?

20

A Your last question to me was, as I recall, did

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the NISUR program cause a reduction in surgical procedures

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based on my information, I indicated to you that based on

23

Dr. Warten's affidavit, that statement was not correct. Based

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on my reading of the evidence and Dr. Warten's affidavit, the

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statement is still not correct in that referring to general

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2 discharges, they are not surgical procedures.

3 Q Have you asked Dr. McCarthy whether adding
4 this program, the Chapter 76 program, on top of the hospital
5 utilization review, did he tell you what marginal additional
6 surgery was unnecessary?

7 A Based on the affidavits that he has presented
8 and based on the studies of his, which I have read, he
9 indicates that approximately -- and I may stand corrected since
10 I do not have his affidavit in front of me, approximately
11 one-seventh of the surgery was not necessary.

12 Q -That was not the question. My question is if
13 you had asked him the question whether adding Chapter 76 on
14 top of the existing hospital utilization review program,
15 there was going to be any additional elimination of surgery?

16 A I have not personally asked him that question.

17 Q Do you know if anyone within the Department of
18 Social Services has asked that question of him?

19 A That is a professional medical jurisdiction are
20 not by contract handled by the New York State Department of
21 Health for the Department of Social Services.

22 Q Do you know if anyone in the Department of
23 Health has asked that of Dr. McCarthy?

24 A To the best of my knowledge, yes.

25 Q What is the response?

1
2 A I'll have to assume it, since I was not the
3 party that talked with Mr. McCarthy. His answer was in the
4 affirmative.

5 Q How long has Chapter 76 now been in effect in
6 New York?

7 A Since the passage of legislation, over three
8 months. Since actual implementation, approximately a month
9 and a half.

10 Q Have you attempted to determine what surgery
11 has been eliminated by the actual implementation of Chapter
12 76?

13 A We have.

14 Q What are the results of that?

15 A We find based on audits conducted in hospitals
16 by our department of audit and quality control, that following
17 implementation of Chapter 76 there has been a reduction in the
18 types of procedures performed and that hospitals are
19 generally following the provisions of Chapter 76 with no
20 significant difficulty.

21 Q And that means that the patients are being
22 turned away from the hospitals; doesn't it?

23 A No, it does not.

24 Q Surgery is not being performed, it means that
25 surgery is not being performed?

1
2 A You're asking me for a guess?

3 Q I'm asking you whether that isn't what is
4 calle d a reduction in surgery, surgery is not performed?

5 A That unnecessary surgery is not performed.

6 Q Surgery for example required by an individual
7 like Raymond Ortega is not being performed?

8 A I have no first-hand knowledge of that.

9 Q If your \$1-million figure may well represent
10 other cases or include other cases, many other cases like
11 those of Jane Doe and Ray Ortega, they are not being operated
12 upon?

13 A That is a conclusion that I can't draw. I have
14 no evidence to support facts one way or the other.

15 Q That could be a figure, could it not, for the
16 amount of surgery that is not being performed --

17 MR. MCMURRY: I object. You're asking for
18 guesses by the witness of things which he has no
19 personal knowledge --

20 MR. SIFTON: Remember the request for
21 possibilities like the ones you had. No further
22 questions at this time.

23 EXAMINATION

24 BY MR. MCMURRY:

25 Q Were Jane Doe or Ray Ortega ever denied

1
2 reimbursement during surgical procedure, to the best of your
3 knowledge?

4 A To the best of my knowledge, no.

5 Q To your knowledge, were they denied surgery?

6 A I don't understand.

7 Q To your knowledge, did a doctor say to them,
8 based on Chapter 76, I don't see how you can get medical
9 assistance for surgery?

10 A It is stated in the doctors' affidavits, yes.

11 (Continued next page.)
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EXAMINATION

BY MR. SIFTON:

RS:jk 3
last

Q With regard to the unnecessary surgery, which you believe will not be performed under Chapter 76, can you first of all tell us how many surgical procedures, how many cases are involved in that figure?

A Without my actual documents at hand, which are in Albany, to the best of my recollection, between fifteen and a thousand cases annually.

Q How about a day?

A I can divide that quickly.

Q Per your one million dollars a day, I take it 65 per cent is represented by surgical expenses?

A That's correct.

Q And how many cases does that involve?

A I'll be honest with you. I can't do the mathematics in my head that quickly. It's possible, though.

Q \$650,000 represents the surgical procedures?

A It's a very complex formula, to go back to that, I can't do it without calculating it.

Q Do you know what kinds of surgery are being eliminated by unnecessary surgery within the \$650,000 figure?

A When you say that, what kinds of surgery?

Q Let me ask you this: In Dr. Wharton's affidavit he referred to electrolysis and hair surgery as being a type

1
2 of unnecessary surgery eliminated. That is one of the types
3 of surgery that is included in your elimination of
4 unnecessary surgery?

5 A First of all, I think there is -- I think it
6 should be made clear --

7 Q Can you just answer that question with regard
8 to electrolysis?

9 A No specific diagnosis, type of condition on
10 any particular patients are being eliminated categorically.
11 It's based on the medical needs of each patient.

12 Q Are there many cases involving electrolysis or
13 surgery or hair involved in that figure?

14 A In which figure?

15 Q In the one million dollar a day figure.

16 A I have no way of knowing.

17 Q How about Dr. Wartens, he refers to 63
18 operations to increase breast size; is that included within
19 the figures?

20 A Breast operations are included in the figure.

21 Q And how about operations to remove tattoos?

22 A They are.

23 MR. SIFTON: Do you have any questions?

24 MR. MC MURRY: Just a few.

25

EXAMINATION

BY MR. MC MURRY:

Q I understand your testimony that all operations to remove tattoos and all operations for breast enlargement were included in this statement?

A No, they are not all included. As I understood his question, were they a type of surgery that was included in our figures. I do not infer that each one of them would be categorically excluded.

Q Do you know of any documented cases or similar Jane Doe or Mr. Ortega cases where compensation was provided under Medicaid?

A According to the figures supplied by the New York City Regional Office of the New York State Health Department, similar cases to Jane Doe and Ortega have happened. The illustrative example contained in the affidavit have been performed in New York City and people have been reimbursed by Medicaid since Chapter 76 was enacted.

Q Do you know any specific examples?

A We have a list at the table. But I do not have it on the stand.

MR. MC MURRY: Would this refresh your recollection?

MR. WARTENS: There are names which identify

1
2 patients on there and it cannot be shown. They cannot
3 be disclosed.

4 MR. SIFTON: I don't think in any event that
5 this witness, who is not a doctor, is in a position
6 to talk about either the case of Jane Doe or the case
7 of other patients who have been seen by persons who
8 are doctors and this really is an inappropriate
9 subject for inquiry.

10 Q Your statements are based on information which
11 has been provided to you by the Department of Health; isn't
12 that correct?

13 A That's correct.

14 Q Division of Statistics and so on?

15 A That's correct.

16 MR. MC MURRY: I have no further questions.

17 Thank you.

18 MR. SIFTON: Thank you.

19
20 _____
DOUGLAS EVANS

21 Subscribed and sworn to

22 before me this day of 1976

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE

Plaintiffs,

-against-

PHILIP TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P. WHALEN,
M.D., as Commissioner of the Department
of Health of the State of New York,

Defendants.
-----x

AFFIDAVIT

State of New York)
County of Albany) SS.:
City of Albany)

James D. Wharton, M.D., being duly sworn, deposes and
says:

1. Deponent is an Assistant Commissioner of the New York
State Department of Health and director of the Division of
Medical Standards.

2. The Department of Health has an active role in Medical
Assistance, including certifying medical standards, surveying of
facilities and professional surveillance, in support of the
Department of Social Services, acting as the single State agency.

3. This affidavit is made in opposition to plaintiff's
motion for preliminary injunction.

4. Plaintiff has made certain allegations as to the propriety of Chapter 76, the Laws of 1976 and the regulations and procedures promulgated thereunder.

5. Plaintiff's allegations are without merit and the relief requested should be denied.

6. Medical assistance for needy persons is a State program. Partial financial reimbursement is available from the Federal government through the Department of Health, Education and Welfare where the State plan submitted by the single State agency meets the requirements contained in Title XIX of the Social Security Act. Payment to the State may be limited by the Secretary of Health, Education and Welfare where he finds there is a failure to comply substantially with the provision of the State plan.

7. From its inception in 1966, the expenditures for Medicaid more than tripled by fiscal 1972/1973. The projected expenditure for the fiscal year ending March 31, 1977 was \$3,000,000,000, an increase of 22 per cent over the actual expenditures for the fiscal year ending March 31, 1975. The expenditure for hospital inpatient services, exclusive of medical fees, was projected as in excess of \$1,000,000,000.

8. It can be demonstrated that a substantial portion of costs result from overutilization and the inappropriate or unnecessary use of that portion of the health care delivery system utilizing third party reimbursement and that this has contributed to the alarming increase in the costs of health care. The State has a compelling interest, contrary to plaintiff's allegations, in

controlling these costs in a program for which the State has administrative responsibility. The State has a responsibility to protect the lives and welfare of its citizens as well. These needs have been recognized at the Federal level also.

9. The Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, chaired by the Honorable John E. Moss, concluded that a program of second opinions before surgery could cut down significantly on unnecessary surgical procedures and save the government millions of dollars. It concluded further:

"Unnecessary surgery wastes lives and dollars. There were an estimated 2.4 million unnecessary surgeries performed in 1974 at a cost to the American public of \$4 billion. These unnecessary surgeries led to 11,900 unnecessary deaths."

(U.S. Government Printing Office, 1976, 64-695)

10. The subcommittee found that surgical payments by the fee-for-service mechanism encourages surgery in questionable situations. The report cites numerous articles which appeared in technical journals indicating that many surgical operations performed in the United States need not have been performed, including a three year "Study on Surgical Services for the United States" under the auspices of the American College of Surgeons and the American Surgical Association.

✓ 11. The subcommittee also indicated that the evidence suggests that up to one-fourth of surgical procedures not performed in hospitals might be performed without hospitalization.

12. Pure reason and logic indicate that unnecessary hospitalization and unnecessary surgery are not consistent with proper health care.

13. Under Chapter 76 and the implementing regulations, the following examples of actual cases from New York State Hospital Utilization Review (NYSHUR) data would not in most instances have been eligible for reimbursement, and with the mechanisms for admission and length of stay authorization would probably not have occurred. Thus, patients would be protected against unnecessary surgery and prolonged hospital stay, and the State would be protected against undue cost.

(a) Sixteen admissions for electrolysis, a simple procedure for removal of hair often done by beauticians, certainly not requiring hospitalization. These cases had an average stay of 4 days.

(b) Sixty-three operations to increase breast size, with an average stay of 5.5 days.

(c) Three operations to remove tattoos.

- (d) Eighty-six hysterectomies on women under the age of 35 without mention of suspected neoplasm or of dilatation and curettage to diagnose the cause of uterine bleeding.
- (e) One hospital which included a skilled nursing facility, yet regularly held patients in acute hospital beds who were ready to transfer to vacant nursing facility beds.
- (f) Of 22 long-stay patients in a teaching hospital, nine were held, by the hospital's written statement, for teaching conferences and rounds. Of 18 short-stay patients, 9 were admitted solely for teaching conferences and rounds.
- (g) Fourteen long-stay patients caused an admitted excess stay of 305 days due to failure to discharge planning and referral to social workers.
- (h) In another hospital, there was an admitted excess of 10 days prior to surgery for one case, and 4 days for another, due to delays in pre-operative workup. In the same hospital, one patient had an 11 day delay in discharge, awaiting physician completion of a nursing home transfer form. Another patient was held 3 days awaiting a surgical consultation before discharge.

14. The results of a 1975 "Moss" committee questionnaire completed by the states indicates that the 1974 surgery rate for Medicaid eligibles was 18,716 per 100,000 persons while that for the total United States population is 7,940 per 100,000.

15. In 1970, a U.S. Senate Finance Committee in its staff report, "Medicare and Medicaid-Problems, Issues and Alternatives" (Medical Assistance Manual § 5-30-10) indicated "States should adopt procedures for prior independent professional approval of elective surgery***"

16. Faced with the malpractice crises Governor Carey appointed a Special Advisory Panel on Medical Malpractice, chaired by William J. McGill, President of Columbia University. This panel stated that if full attention is to be paid to the objective of prevention of medical injury it must be in the context of major efforts to improve the quality of care. The panel went on to say that a first step in the new direction is to begin curtailing unnecessary hospitalization by requiring second opinions or other methods of verification in the case of elective surgery to be compensated by third party reimbursement, and recommended that such requirement be statutory.

17. Utilization control as delineated by the above has two basic purposes: (1) to insure that consumers receive high-quality medical care, and (2) to control program costs by preventing unnecessary use.

18. Spiraling costs have jeopardized the basic purpose of the initial enactment of Medicaid, that of providing medical assistance for needy persons. One cause of the high hospital costs was the State's undertaking to provide virtually any type of inpatient service, for any period certified by a physician to be medically necessary. The Governor and the Legislature have recognized that unnecessary surgery and excessive lengths of stay under Medicaid were threatening the capacity to provide necessary surgery and hospital stays.

19. Chapter 76 of the Laws of 1976 was responsive to these concerns.

20. The plaintiffs have placed before the Court the validity of bill §§ 3 and 4 of such Chapter.

21. Bill § 3 amends Social Services Law § 365-a(5) to provide:

5. (a) Medical assistance shall include surgical benefits for emergency or urgent surgery for the alleviation of severe pain, for immediate diagnosis or treatment of conditions which threaten disability or death if not promptly diagnosed or treated.

(b) Medical assistance shall include surgical benefits for certain surgical procedures which meet standards for surgical intervention, as established by the state commissioner of health on the basis of medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with such surgical intervention.

(c) Medical assistance shall include surgical benefits for other deferrable surgical procedures specified by the state commissioner of health, based on the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function, or cause severe pain; provided, however, such procedures shall be included in the case of in-patient surgery, except surgery authorized pursuant to paragraph (a) of this subdivision, only when a second written opinion is obtained from a physician, or as otherwise prescribed, in accordance with regulations established by the state commissioner of health, that such surgery should not be deferred.

(d) Medical assistance shall include a maximum of one patient day of pre-operative hospital care for surgery authorized by paragraphs (b) or (c) of this subdivision; provided, however, that with respect to specific surgical procedures which the state commissioner of health has identified as requiring more than one patient day of pre-operative care, medical assistance shall include such longer maximum period of pre-operative care as such commissioner has identified as necessary.

(e) Medical assistance shall not include any in-patient surgical procedures or any care, services or supplies related to such surgery other than those authorized by this subdivision.

22. Bill § 4 amends Social Services Law § 365-a(2)(b) to require that Medicaid providers of hospital and nursing home care qualify under Title XVIII of the Social Security Act and to require that:

"***in-patient care, services and supplies in a general hospital shall not exceed such standards as the commissioner of health shall promulgate but in no case greater than twenty days per spell of illness during which all or any part of the costs of such care, services and supplies are claimed as an item of medical assistance, unless it shall have been determined in accordance with procedures and criteria established by such commissioner that a further identifiable period of in-patient general care is required for particular patients to preserve life or to prevent substantial risks of continuing disability."

23. In the New York State Medicaid program approximately 12 per cent of patients now have hospital stays beyond 20 days. This should be compared with 8 per cent for the eastern part of the nation in data of the nationally reputable Commission on Professional and Hospital Activities. It is also significant that 25 states have established length of stay limits, eight with limits shorter than 20 days.

24. The New York State Hospital Utilization Review program (NYSHUR), a Medicaid review of hospital utilization data, was announced November 5, 1973 and implemented January-March, 1974.

Before any followup actions of any kind, there was a notable acceleration of discharges of long-stay patients from 12 hospitals in one region of the State, the first region in which the system was implemented. It is especially significant that 23 of these patients were discharged by the hospitals to home after stays ranging from 60 to 1,036 days. When, after such long hospital stays, a patient is discharged to home rather than a skilled nursing facility or intermediate care facility, there is a serious question concerning the actual provision of acute hospital care until the date of discharge. Nine were transferred to long-term care facilities after stays ranging from 68 to 1,242 days. Most significant is the fact that mere knowledge of the collection of surveillance data resulted in this acceleration of discharges. This accelerated discharge pattern was not observed previously nor has it reoccurred.

25. It has also been demonstrated that prolonged hospitalization may cause unwarranted and unnecessary dependence by the patient upon hospital resources and personnel and may result in a breakdown of the patient's own future ability to resume normal functional capability for independent living.

26. In view of the adverse effect of unnecessary surgery upon Medicaid beneficiaries individually and the Medicaid program generally as well as the excess costs incurred through unnecessary use of hospitals, the right and compelling interest of the State to impose administrative controls on surgery and length of stay is self evident. Additionally, there is the obligation of the State to supervise and control the expenditure of public monies. The administrative controls are reasonable and provide numerous important safeguards for the patients.

27. The State does not seek to eliminate reimbursability for surgical procedures and associated care and services as asserted by Doctor Koff. Rather, for the protection of both patients and taxpayers, the State seeks to limit reimbursability to care and services which are necessary, of acceptable quality, efficient and economical.

28. It is noted that in quoting the provisions (§ 6 of Koff affidavit) of 45 CFR 249.10(a)(5)(i), Doctor Koff has omitted the last sentence which states, "Appropriate limits may be placed on services based on such criteria as medical necessity or those contained in utilization or medical review procedures."

29. While it may be unquestionable that a given diagnosis, type of illness or condition of the patient requires treatment, the best professional choice of treatment may involve

selection from numerous acceptable modalities. One surgical procedure is weighed against others, and against more conservative medical management. In the process timeliness and the balance between risk and benefit for the patient must also be considered. Given the substantial risk to the patient and abuses in unnecessary surgery, and recognizing the need for competent professional judgment on such matters, the State has followed numerous recommendations that second opinion be required in cases of proposed surgery which is neither urgent nor emergency. The State has sought assistance from medical school faculties and surgical specialty societies in establishing methods to obtain the necessary competent judgments. Similarly the State has sought assistance in developing objective criteria for intervention which would in specific instances obviate the need for second opinions. The limitation cannot be considered arbitrary in face of available evidence of abuses. Neither is the limitation based solely on determinations of diagnosis, type of illness or condition. They are based rather on medical necessity, which leaves to competent surgical specialists, in their second opinions, the judgment concerning necessity of a specific surgical procedure to protect life or essential function or to prevent severe pain.

30. Doctor Rosenberg, in Par. 4 of his affidavit, says, in the event that such surgical procedures cannot be compensated pursuant to Medicaid, most if not all Medicaid patients will be unable to have such procedures performed and physicians like himself will be unable to carry them out except upon an ad hoc charitable basis. Doctor Rosenberg assumes that the actual care which he describes in his argument would not be coverable under the Medicaid program.

31. In the case of plaintiff Jane Doe described by Doctor Rosenberg, dilatation and curettage would automatically qualify for coverage under Part 85.1 as a surgical diagnostic procedure to establish prompt diagnosis without which there may be failure to recognize a condition threatening disability or death.

32. The remainder of cases contained in the plaintiffs' affidavits are only illustrative in nature and as such fail to demonstrate in the case of specific beneficiaries that surgical procedures have been disapproved and that either life has been threatened or that actual and substantial risk of continuing disability have been visited upon medical assistance recipients. In any event, the illustrative cases demonstrate an unwillingness on the part of the physician plaintiffs to avail themselves of established administrative procedures and remedies and thus assure

their hypothetical patients of full access to benefits available under the Medical Assistance program.

33. In the cases which Doctor Koff cites (§ 11), he himself sets forth the bases upon which he might, if rendering second opinions, weigh the necessity for surgery on a non-deferred basis. Assuredly hemorrhoids which either bleed significantly or cause significant discomfort would necessarily require surgery. Certainly any benign tumor of the vulva, if truly interfering with essential function, should have relief which may require surgery. Umbilical hernias of the type described, may be properly treated only by surgery. On the other hand, medical prudence may often dictate, as also true of hemorrhoids, that non-surgical management is the wiser choice, incurring less risk and discomfort to the patient. Joint cartilage surgery should certainly be performed, but only where expert specialist judgment concurs that the procedure should be performed on a non-deferred basis.

34. A cystocele such as Doctor Rosenberg describes [§ 17(1)], with loss of bladder sphincter control, and therefore incontinence, certainly represents a loss of essential function. If a second opinion from a competent specialist were requested,

which has apparently not been done, it is highly improbable that the consultant upon review of the record and examination of the patient would fail to confirm the necessity for the surgery.

35. Condylomata accuminata, in Doctor Rosenberg's own words (§ 7), are in some instances so large as to require surgical removal. This must mean that in other instances they are not so large as to require surgical removal. The required second opinion would certainly have to consider this factor. Doctor Rosenberg also says that such lesions are unsightly, causing irritation, itching and interruption of normal sexual activity. Certainly, interference with normal sexual activity is a loss of essential function. Significance of the irritation and itching would have to be weighed by the second opinion consultant, which has apparently not occurred.

36. Ovarian cysts are cited by Doctor Rosenberg (§ 7) as sometimes becoming malignant. He suggests that where diagnosis warrants, surgical removal is good preventive medicine. It is exactly on just such a point that the second opinion consultant would be expected to arrive at a decision to confirm or reject the necessity for the proposed surgery.

37. As stated above with respect to Doctor Koff's arguments, the State does not eliminate reimbursability for certain deferrable surgical procedures, but rather, seeks to limit reimbursability to care and services which are necessary, of acceptable quality, and are efficient and economical. In the case of a deferrable surgical procedure the State requires the assurance of competent specialist second opinion for this determination. In several of the cases which Doctor Koff cites he himself has set forth the very criteria upon which the second opinion consultant would make his judgment.

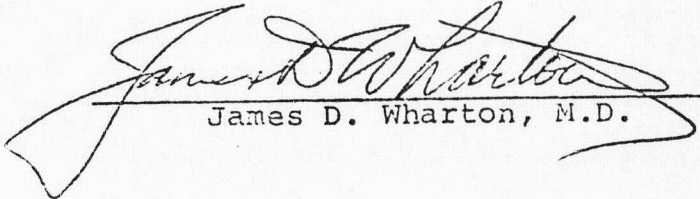
38. In all illustrative instances presented by the physician plaintiffs the following points should be observed:

(a) While it is true that pain is a subjective appraisal which can be made only by a patient, every physician must, however, attempt to evaluate the patient's appraisal before undertaking surgery.

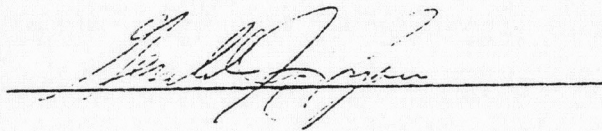
(b) Similarly, essential function is a determination which must be left to physician judgment. Certainly, however, work, sexual function and procreation are among these essential functions.

The State, as payor, must be satisfied with respect to the application of necessary limitations. Therefore, the State must have access through professional personnel, either physicians or nurses under their supervision, to information about proposed surgery and related services. Such information always has the traditionally required protections of confidentiality.

It is respectfully requested that the order sought by plaintiffs enjoining the enforcement or implementation of Chapter 76 be denied.


James D. Wharton, M.D.

Sworn to before me this
20th day of August, 1976.



UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE,

Plaintiffs,

- against -

PHILIP L. TOIA, as Commissioner of the
Department of Social Services of the
State of New York and ROBERT P. WHALEN,
M.D., as Commissioner of the Department
of Health of the State of New York,

Defendants.

AFFIDAVIT IN
OPPOSITION TO
A PRELIMINARY
INJUNCTION

STATE OF NEW YORK }
COUNTY OF ALBANY } ss:
CITY OF ALBANY }

HUGH O'NEILL, being duly sworn, deposes and says:

1. I am Deputy Commissioner for Program and Policy
for the New York State Department of Social Services. My re-
sponsibilities include supervision of the Division of Medical
Assistance of the New York State Department of Social Services.

2. I am familiar with the facts, circumstances and
issues in this litigation as they relate to the Division of
Medical Assistance.

3. I make this affidavit in support of defendant
Commissioner Philip L. Toia's opposition to plaintiff's motion
for a preliminary injunction.

4. The plaintiffs in this action claim that surgical
limitations authorized by Chapter 76 of the Laws of 1976 vio-
late Federal regulations by improperly limiting inpatient
hospital services, physicians services and lengths of inpatient
stay available to Medicaid patients. Plaintiffs also claim that
the language contained in the law and implementing regulations

is overly vague. The Health Department is alleged to have implemented standards in a manner that is without rational basis. Furthermore, the requirement of a second opinion in certain situations as provided in standards set by the Commissioner of the Department of Health is said to violate the physician's right to practice his profession.

5. Each of plaintiffs' claims are without merit:

A. Plaintiff doctors and Jane Doe assert that medical assistance has been denied to Jane Doe because the care needed is deferrable. In point of fact however if Jane Doe has the symptoms described in paragraph 9 of the complaint herein, she would be eligible for immediate care under 10 NYCRR 85.1(a)(11) because her condition requires "prompt diagnostic procedures necessarily performed on an inpatient basis..." such as a dilation and curettage. As far as known by defendants none of the available actions have been taken by the physician herein. The State Commissioner of Health or his designee has not ruled the admission inappropriate. Jane Doe's physician has not taken actions necessitating review of any kind by any party. Furthermore, contrary to plaintiff's allegations regarding the approvability of Jane Doe's condition for treatment, cases similar to Jane Doe's have been undertaken and approved under the provisions here in issue at Cabrini Hospital, Roosevelt Hospital and Bellevue Hospital. Thus plaintiff physicians and Jane Doe have not properly exercised their administrative rights and remedies, consequently have no cause of action and should be dismissed from this proceeding.

A-a. On August 20, 1976, defendants were served with a supplemental summons dated August 20, 1976 and a first amended complaint in this action (undated). Paragraph 10 of same introduces plaintiff Ramond Ortega who is a seventeen year old recipient of Aid to Dependent Children. Plaintiff Ortega has suffered very serious burn scars which presently cause him severe social embarrassment and emotional trauma plus further physical

debilitation. Plaintiffs assert that since the condition as described does not threaten death or disability and will not cause severe pain or threaten life or essential function, Mr. Ortega is not eligible for inpatient surgery under the provisions here in issue. It is not clear whether Mr. Ortega has applied for relief or not. However based solely on the scanty facts presented it would appear that an essential function has been impaired if Mr. Ortega's ability to obtain employment and the condition further threatens recurrent conjunctivitis. Furthermore based solely on the facts herein presented and with little detail or time to study this matter, it would appear that Mr. Ortega is eligible for the care requested as it is medically necessary.

B. The plaintiffs' comments indicate a misconception of Chapter 76. Plaintiffs indicate there is blanket elimination of all surgery that is not immediately necessary to save life, etc. This however, is not so. The purpose of Chapter 76 of the Laws of 1976 is to further certain legitimate interests of New York State; namely, to limit unnecessary surgery to protect patients in the Medicaid program and attempt to limit Medicaid costs in response to an "emergency fiscal crises of staggering proportions" being faced by the State and local governments (C. 76 L. 76, section 1).

The need for the controls contemplated by C. 76 L. 76 has been recognized in Title XIX of the Social Security Act. Section 1902(a)(30) sets forth as a requirement of a State plan that it must:

"(30) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in Section 1903(1)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy, and quality of care;"

Chapter 76 sets forth three categories of surgery:

(1) emergency or urgent surgery for the alleviation of severe pain, for immediate diagnosis or treatment of conditions which threaten disability or death if not properly diagnosed or treated.

(2) surgical procedures which meet standards for surgical intervention established by the Commissioner of Health on the basis of medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with such surgical intervention.

(3) deferrable surgical procedures based on the likelihood that deferral for six months or more may jeopardize life or essential function or cause severe pain, provided that the need for the procedure has been confirmed by a second written opinion that such surgery should not be deferred.

In those instances where a patient's physician determines on an emergency or urgent basis that it is necessary immediately to admit a recipient to a hospital for a surgical procedure in order to preserve life, alleviate severe pain or prevent substantial risk of continuing disability, such admission is at the discretion of the physician and is subject to review after such admission, and presumably surgical intervention, has been effected.

In other instances where, in the opinion of the patient's physician, the need for hospitalization exists but is not urgent, immediate admission is not medically necessary. In such cases, Chapter 76 requires that prior to admission for surgical treatment of such conditions, a confirming second opinion ~~be~~ obtained from a qualified medical specialist prior to hospitalization and performance of such deferrable surgery. The primary decision as to necessity or deferrability is, in all instances, made by the patient's physician. These provisions do not interfere with the right of a Medicaid recipient to receive necessary care and treatment, but only requires confirmation of the necessity for the specific surgical procedure prior to admission.

C. The policy of this Department has been and continues to be to provide assistance for the provision of all

necessary inpatient medical services, as mandated by Federal Law, to Medicaid recipients. This is consistent with Federal regulations which provide that:

"...appropriate limits may be placed on (medical) services based on such criteria as medical necessity (emphasis added)..."
45 CFR 249.10(a)(5)(i)

D. The provisions here in issue are neither restrictive of a physician's right to practice his profession nor are they defectively vague. In all state programs designed to provide services to the indigent throughout the years, and particularly since inception of the Title XIX program the State, in response to federal mandates, has placed limits on the scope of benefits available to recipients. The present regulations constitute, therefore, a legitimate extension of sound past legislative, regulatory and administrative practices.

Not all patients admitted to a hospital expect nor should they, to receive all "items and services ordinarily furnished by the hospital for the care and treatment of inpatients provided under the direction of a physician" (45 CFR 249.10(b)(1)). Likewise, the same patient needing physicians' services will not need all "those services provided, within the scope of his [physician's] practice as defined by State law...".

45 CFR 249.10(b)(5) Instead, professional decisions are required to decide which course of treatment is medically necessary. This, concomitantly excludes all unnecessary treatment. New York State law and regulations which restrict physicians and/or hospital services to those which are medically necessary are thus consistent with Federal regulations and rational medical practice. Furthermore, so as to provide sufficient latitude for professional judgment in multitudes of unforeseeable situations, the definitional terms used such as "severe pain" are broad, though far short of defective vagueness. Rather than restrict proper medical practice, these definitions are designed to encourage sound professional discretion.

E. The Department of Health, the State agency responsible for establishing and maintaining health care standards, has chosen the standards here on a rational basis. In each case of limitation, the basis has been the legitimate and compelling State interests set forth by the State Legislature of protection of patients from unnecessary treatment where at the same time attempting to reduce costs and cost reduction. The specific procedures that have been listed by the Commissioner of Health have been selected on the basis of studies conducted by recognized medical experts in the public and private sector which have established patterns of abuse of the Medicaid system. This fulfills the legitimate interests of New York State to protect patients from needless surgery and taxpayers from abuse of assistance.

F. Further, while not specifically stated in Chapter 76, but as in fact developed in Department of Health regulations and operating instructions, provisions of second opinions including physical examination will be made by physicians.

G. It has been and continues to be the policy of this Department to provide payment for medical care and services "...sufficient in amount, duration and scope to reasonably achieve their purpose" (emphasis supplied 45 CFR 249.10(a)(5)(i)). Although one and twenty day limitations have been established for pre-operative stays and total inpatient time, respectively, there are regulatory exceptions wherever "medically necessary."

THEREFORE, for the above stated reasons, plaintiffs' application for injunctive relief should be denied.

S/ H. O'NEIL

HUGH O'NEILL
DEPUTY COMMISSIONER FOR
PROGRAM AND POLICY

Sworn to before me this
23rd day of August, 1976

J. B. RANDES

NOTARY PUBLIC

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
THE MEDICAL SOCIETY OF THE STATE OF :
NEW YORK, a New York not-for-profit :
corporation, MORTON M. KOFF, M.D., :
MILTON ROSENBERG, M.D. and JANE :
DOE, :

Plaintiffs, : AFFIDAVIT IN OPPOSITION
: TO A PRELIMINARY
-against- : INJUNCTION

PHILIP TOIA, as Commissioner of the :
Department of Social Services of :
the State of New York and ROBERT P. :
WHALEN, M.D., as Commissioner of :
the Department of Health of the :
State of New York, :

Defendants. :
-----X

STATE OF NEW YORK)
: SS.:
COUNTY OF NEW YORK)

EUGENE G. MCCARTHY, M.D., M.P.H., being duly sworn,
deposes and says:

1. Deponent is an associate clinical professor at
the Cornell University Medical College, Department of Public
Health in New York City and has served in that position since
1970.

2. Deponent has engaged in the study of second
opinion consultation procedures which involve pre-operative
screening of patients and which relies upon a surgeon's
re-evaluation of the need for, or of operation at the next
therapeutic step in cases of patients who have been informed
by at least one physician that an operation is required.

BEST COPY AVAILABLE

3. Beginning in 1970 and continuing to the present, your deponent has conducted research, prepared and has published studies and conducted lectures at various medical schools, and addressed Industrial Groups and municipal organizations on Second Opinion Consultation Programs.

In addition your deponent has testified on this subject at Congressional hearings.

4. Second Opinion Consultation Programs are classified as either voluntary or mandatory.

Generally mandatory programs require the insured member to have a second consultation prior to his admission for in-hospital elective surgery, sometimes referred to as deferrable surgery. Such surgery has been defined as essentially all non-emergency surgery.

Voluntary programs leave to the insured the judgment whether he wishes to elect this new benefit of a second opinion.

In both programs, the total cost of the physician consultation as well as ancillary services costs are fully paid by the respective medical insurance or comparable plans.

5. In the Spring of 1972, to carry out a Second Opinion Surgical Consultation Program for several Taft-Hartley Welfare Funds, the Cornell University Medical College's Department of Public Health established a grid of surgical consultants representing all of the surgical subspecialties in the greater New York area. These surgical consultants were all board-certified specialists affiliated with the major teaching institutions and several of the larger community suburban hospitals in the greater New York area.

6. Historically, the initial panel of board-certified specialists was created through my contacting the chiefs of the services of all the major medical schools and some of the teaching hospitals in New York and several of the suburban community hospitals. Our panel which is now in excess of 400 surgeons is a mixture of both academic based surgeons as well as community based surgeons. The emphasis from the very beginning was to structure a panel which mirrored the surgical community in our area. The predominance of our panel membership is, therefore, composed of community based practicing surgeons. Within the last few months, we have augmented our panel both in New York and New Jersey with the active assistance of the respective chapters of the American College of Surgeons.

7. We first presented our early research efforts in the December 19, 1974 New England Journal of Medicine, a copy of which is annexed hereto as Exhibit A.

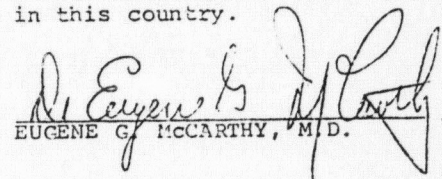
8. The results of our expanded and subsequent research in this field are incorporated in the Dorothy R. Eisenberg Lecture delivered at the Department of Surgery of the Harvard Medical School on June 12, 1976, a copy of which is annexed hereto as Exhibit B, and in the presentation made at the American Federation for Clinical Research, Clinical Epidemiology, Exhibit C.

9. The implementation of the program conducted and the survey results reflected in Exhibits A, B, and C lead us to the following conclusions:

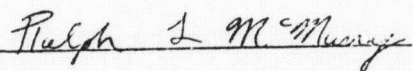
(I) A prospective second opinion elective surgical program utilizing board-certified surgeons after a careful follow up evaluation of the non-confirmed case for at least one year to four years, demonstrates that in the voluntary programs, one out of four screened patients, and in the mandatory

programs, one out of seven and a half screened patients, appear to be permanently deferred. The higher percentage of non-confirming consultations in voluntary programs is influenced by the greater likelihood that a doubting patient will seek a second opinion.

(II) The impact of our current findings more than justifies the wide adoption of the mechanism of second opinion elective surgery for appreciable improvement in the quality of care and effective cost utilization. The translation of this research project to medical care practice can significantly effect the delivery system of care in this country.


EUGENE G. MCCARTHY, M.D.

Sworn to before me this
2nd day of August, 1976



Assistant Attorney General
of the State of New York

SPECIAL ARTICLE

**EFFECTS OF SCREENING BY CONSULTANTS ON RECOMMENDED ELECTIVE SURGICAL
PROCEDURES**

EUGENE G. MCCARTHY, M.D., M.P.H., AND GERALDINE W. WIDMER, R.N., M.P.H.

SPECIAL ARTICLE

EFFECTS OF SCREENING BY CONSULTANTS ON RECOMMENDED ELECTIVE SURGICAL PROCEDURES

EUGENE G. MCCARTHY, M.D., M.P.H., AND GERALDINE W. WIDMER, R.N., M.P.H.

Abstract To assess the need for elective operations recommended to a group of union members, 1356 self-selected patients were re-examined by board-certified specialists. Approximately 24 per cent of all procedures recommended were not confirmed. An additional 2.1 per cent were confirmed but did not require hospitalization. The proportion of cases not confirmed in each of the surgical specialties were as follows, in descending order of frequency of utilization: general surgery, 16.4 per cent; gynecology, 31.4

per cent; orthopedics, 40.3 per cent; ear, nose and throat, 16.3 per cent; ophthalmology, 28.2 per cent; and urology, 35.8 per cent. Program operating costs were about one eighth of the estimated savings from hospitalizations not required. Because of the cost savings and the demonstrated percentage of operations not approved, presurgical screening programs appear to have a substantial benefit for any insured population. (N Engl J Med 291:1331-1335, 1974)

FOR several years, researchers using a variety of methods have questioned the necessity of some of the surgical procedures performed in the United States. Lembcke¹ and others have demonstrated and recommended that the serious implications of unnecessary operations and of unnecessary hospitalizations can be dealt with by such techniques as utilization review, prior authorization, and medical auditing. Concern with the quality and costs of medical care has resulted in the Medicare (Title XVIII) and the Medicaid (Title XIX) reimbursement requirements that some form of quality review take place. At present, no universally acceptable methods have been developed to assess what proportion of operations is necessary or to reduce unwarranted procedures effectively.

To quantitate the proportion of unwarranted operations, several investigators have compared the surgical utilization rates of different geographic regions and of populations with different reimbursement mechanisms.²⁻⁴ In general, surgical rates appear to be higher when the rate of physicians performing operations is higher, when fee-for-service, rather than pre-paid, payment mechanisms are used, and when the number of beds per person is higher. Recent work comparing physicians and their spouses (a group who presumably would use good judgment in obtaining surgical care) to other

groups of comparable education and socioeconomic status yielded the interesting result that physicians and their spouses had higher surgical rates.⁵ Another approach, retrospective studies of hospital records used by Trussell and Morehead,⁶ showed that a high percentage of surgical procedures were not indicated, but the same method, when used by the Quality of Care Committee of the New York Medical Society, yielded opposite results.^{7,8}

Monitoring the quality of surgical care has traditionally been done in a hospital setting by retrospective chart review or by a panel of specialists reviewing post-operative cases. We describe a preoperative screening program that is prospective and relies on a surgeon's re-evaluation of the necessity of an operation as the next therapeutic step in the care of patients who have been informed by at least one physician that an operation is required.

Presurgical screening programs were established by the United Storeworkers Union and by District Council 37 of the American Federation of State, County and Municipal Employees. Concern with both the quality of care that members were receiving and the questionable necessity for a proportion of the expenditures for hospitalization led the two unions to provide a mechanism for members about to undergo elective* surgical procedures whereby

*Elective surgery has been defined by the membership of the unions and by the program's personnel during the course of the program's development. Essentially all non-emergency surgery is considered elective. Persons needing emergency surgery, such as results from trauma, would not be accepted for screening.

From the Department of Public Health, Cornell University Medical College, 1300 York Ave., New York, NY 10021, where reprint requests should be addressed to Dr. McCarthy.

they might first see a board-certified specialist to review the need for the operation.

DESCRIPTION OF THE PARTICIPATING FUNDS

In 1971, the Cornell School of Industrial and Labor Relations was approached by the trustees of the health and welfare plans of several unions for assistance in developing their health policy. The Cornell School of Industrial and Labor Relations, in turn, asked for technical assistance from the New York Hospital — Cornell University Medical College Department of Public Health. One of the major results of this dialogue on union welfare policy was the development of the presurgical screening programs.

In February, 1972, the Storeworkers Health and Welfare Fund began a program requiring presurgical consultation for all members who had been told that they needed elective surgical hospitalization. Storeworkers Health and Welfare Fund, Locals 2, 3 and 5, covers approximately 20,000 members and their dependents through a self-insured program providing hospitalization and care by a physician. The Fund is directed by an equal number of union and management trustees responsible for the administration of pension and health and welfare programs in accordance with the Taft—Hartley Law. The Storeworkers' membership is approximately 70 per cent female, with its members living in or around New York City.

Storeworkers' members were informed that hospital and physician costs incurred by themselves or their dependents would not be paid if they had not requested the presurgical screening office for a consultant appointment before their hospitalization. Although the program was intended to be compulsory, exceptions were made when the beneficiary lived too far away from the offices of the consultant, or when the waiting period for an appointment with the consultant was too long. The proportion of persons enrolled in the program but excused for the above reasons is 16 per cent.

In July, 1972, District Council 37 began a presurgical consultation program on a voluntary basis. Physicians' services for approximately 200,000 members and dependents are covered under one of the New York City employees' three basic plans: Health Insurance Plan of Greater New York (HIP); Blue Shield (Major Medical); and Group Health Incorporated (GHI). Hospitalizations are covered by a 21-day full-benefit Blue Cross contract.

In each of the union health and welfare offices, program personnel arrange, at members' requests, appointments with appropriate surgical specialists. The member is asked to have his personal physician complete a form indicating the nature of the surgery proposed and the existence and results of any laboratory or x-ray studies. Forms are returned by approximately half the personal physicians. Results of the consultation are conveyed through the member to the personal physician. The consulting surgeons have the authority to perform any laboratory or x-ray studies that they think are required to determine whether an operation is justified as the next

therapeutic step in the care of the given member. The charge for the consultation and any required laboratory or x-ray services is borne by the respective health and welfare funds. The results of the consultation are given to the member by the consulting surgeon and are also sent back to the appropriate union office. The consultations are performed by the surgeons affiliated with the surgical departments of several large teaching hospitals located in New York City and by certain board-certified surgeons practicing in Northern New Jersey and Long Island.

Before we discuss the experience of these presurgical screening programs, several points deserve emphasis. As a result of a number of factors, the findings presented here cannot be applied to the general population undergoing elective operations. The union leadership of District Council 37 decided that voluntary participation was necessary. Although the Storeworkers' program is only partially compulsory, a review of the 16 per cent excused cases does not indicate a bias because of diagnosis, age, or sex.

The proportion of the total surgical experience of the two unions represented by persons who have preoperative screening is also unknown. In both unions, members and their dependents, although eligible, are not required to use the union health coverage but may instead use other coverage or pay out-of-pocket. For District Council 37 members choosing the union coverage but not the presurgical screening program, the method of claims payment by the carrier makes it impossible to retrieve information concerning their elective surgical experience, and the total elective surgical experience for District Council 37 is not ascertainable.

PROGRAM FINDINGS

Data are available concerning experience of 602 members of the Storeworkers Union over 28 months, and of 754 members of District Council 37 over 23 months. This number of presurgical consultations represents only a fraction of the total surgical experience of these groups during the given time frame. The rate of non-obstetric surgical procedures in short-stay hospitals for the Northeast United States in 1968 was 7.3 per 100 population.⁹ It should be noted, however, that a projection of this rate to determine what proportion of the eligible population was seen is not correct, since emergency procedures and procedures on persons 65 years of age and over generally were excluded from the screening program. If it were available, an age-adjusted nonemergency surgical rate for an employed population would provide a good base line for comparison.

Although the program utilization by the Storeworkers maintained a constant rate, an annual increase of 25 per cent in the District Council 37 members requesting presurgical screening was observed from the first to second years and is attributed to improved advertisement of the program and patients' recommendations.

Approximately one fifth of the operations recommended to the screened Storeworkers' members, as compared with one third of those recommended to the screened District Council 37 members, were not confirmed (Table 1).

This difference is statistically significant* ($\chi^2_1 = 29.73$, $p < .0005$) and may be related to the fact that use of the program is entirely voluntary for District Council 37 members and compulsory for Storeworkers. Members who elect to have a consultation before an operation might have greater reservations regarding the necessity for surgery, for reasons with which the consultant might agree.

Not all persons who were advised to have an operation by both the original and consulting surgeons required hospitalization. More than 3 per cent of the screened District Council 37 members and 1 per cent of the Storeworkers had procedures such as the removal of moles and small cysts performed on an outpatient basis. A substantial component of all surgical procedures scheduled for hospitalizations, with all the attendant costs and inconvenience, has been reported as feasible on an outpatient basis.¹¹

Table 1. Confirmation of the Need for Operation by Union.

UNION	CONFIRMED (%)		NOT CONFIRMED (%)
	HOSPITALIZATION REQUIRED	HOSPITALIZATION NOT REQUIRED	
District Council 37 (754)*	68.6	1.0	30.4
Storeworkers (602)	79.2	3.2	17.6

*Figures in parentheses denote no. of union members.

Women more frequently than men took advantage of presurgical screening. This finding would be expected for the Storeworkers' program, in which the proportion of female members screened — 73 per cent — is roughly the same as that of the members who are female. District Council 37, on the other hand, had a disproportionately high rate of females using the program; 66.6 per cent of screenees were women as compared with approximately 50 per cent of the total membership. The higher utilization of the program by women in District Council 37 seems consistent with what is known generally about the higher utilization of physician services by women.

Roughly 75 per cent of all persons screened were in the group from 22 to 64 years of age. The age distribution of both confirmed and not confirmed cases is approximately the same. The program was used primarily by the member and his or her spouse, and only rarely by dependent children.

In District Council 37, persons with general surgical problems used the program less often, and persons with orthopedic problems used it more often than in Storeworkers (Table 2). A chi-square test was performed to determine if the cases screened had a common distribution according to surgical specialty for the two unions. The distributions were found to be significantly different $\chi^2_8 = 72.37$, $p < 0.0005$. Differences in the distributions may be the result of a difference in the sex composition of the

Table 2. Distribution of Cases According to Surgical Specialty for Both Unions.

SPECIALTY	DISTRIBUTION (%)	
	STOREWORKERS	DISTRICT COUNCIL 37
All specialties	100.0	100.0
General surgery	48.7	32.1
Gynecology	24.9	22.9
Orthopedics	6.3	14.1
Ear, nose, & throat	8.1	11.4
Urology	4.0	7.6
Ophthalmology	6.1	5.3
Others	1.8	6.6

unions, and of self-selection by patients in District Council 37.

Chi-square tests were performed to compare the proportions of confirmed cases in each specialty for the two unions (Table 3). Gynecologic cases were more likely not to be confirmed among members of District Council 37 than among the Storeworkers ($p < 0.01$). For all other specialties, there was no significant difference in the proportion confirmed in the two unions at the $p < 0.01$ level.

Comparisons of the proportions of confirmed and not confirmed cases were possible for only two of the four most frequent operative procedures (Table 4). The proportions of screened hysterectomy cases that were confirmed for the two unions were not significantly different. However, the proportion of screened dilatation-and-curettage procedures confirmed was significantly lower for District Council 37 ($p < 0.01$).

The overall proportion of hysterectomies that were not confirmed, 32.0 per cent, is the same proportion found by Trussell and Morehead to be unnecessary or unsatisfactory in a retrospective record audit.⁶ The proportion unconfirmed for each of the four diagnoses is substantially less than the proportion implied to be unnecessary for female surgical procedures (including mastectomy, non-maternal dilatation and curettage, and hysterectomy) and cholecystectomy for the federal employees enrolled in Blue Shield.¹² In contrast, the Medical Society of the County of New York report of a quality audit indicates for hysterectomies that 3.2 per cent were unacceptable and

Table 3. Confirmation for Operations According to Surgical Specialty and Union.

SPECIALTY	STOREWORKERS			DISTRICT COUNCIL 37		
	TOTAL NO.	% CONFIRMED	% NOT CONFIRMED	TOTAL NO.	% CONFIRMED	% NOT CONFIRMED
All specialties	602	82.4	17.6	754	69.6	30.4
General surgery	293	86.7	13.3	242	80.2	19.8
Gynecology*	150	78.7	21.3	173	59.5	40.5
Orthopedics	38	65.8	34.2	106	57.5	42.5
Ear, nose & throat	49	89.8	10.2	86	80.2	19.8
Urology	24	70.8	29.2	57	61.4	38.6
Ophthalmology	37	78.4	21.6	40	65.0	35.0
Others*	11	72.7	27.3	37	78.4	21.6

* χ^2_1 for gynecology, 12.97 ($p < 0.0005$).

**Others* did not have enough cases in each cell for significance testing with chi-square. All other specialties were not significant at the $p < 0.01$ level.

*Chi-square tests of differences and test of common distribution comparing proportions for the two unions were done in this study with use of $\chi^2 = \sum \frac{(O-E)^2}{E}$, with degrees of freedom = $(r-1)(c-1)$.¹⁰

Table 4. Confirmation for the Four Most Frequently Screened Surgical Procedures According to Union.

PROCEDURE	STOREWORKERS			DISTRICT COUNCIL 37		
	TOTAL NO.	% CON-FIRMED	% NOT CON-FIRMED	TOTAL NO.	% CON-FIRMED	% NOT CON-FIRMED
Hysterectomy	49	74.5	25.5	105	66.7	33.3
Dilatation & curettage*	72	83.3	16.7	37	56.8	43.2
Mastectomy, mastectomy, and other procedures on the breast	49	89.8	10.2	42	78.6	21.4
Cholecystectomy	34	88.2	11.8	33	87.9	12.1

* $\chi^2=9.857$, $p<0.003$. Cholecystectomy & mastectomy, mastectomy, & other procedures on the breast did not have enough cases in each cell to permit a chi-square test of significance. Difference in the proportion confirmed for hysterectomy was not significant at the $p<0.05$ level.

7.1 per cent were questionable.⁷ Another Medical Society report indicates that the care of 0.4 per cent of patients who had cholecystectomies was unacceptable.⁸

A third consultation was permitted at the member's request by both unions for unconfirmed cases. Of the 335 persons for whom operation was not confirmed, less than 10 sought a third opinion. In addition, the member had the privilege, at his or her discretion, of requesting that the surgical procedure be performed by the consultant. Thirty per cent of the confirmed operations were performed by the consultant at his hospital.

DISCUSSION

The findings of this report should be considered preliminary. Several questions need to be explored before the full value of the screening program can be determined. It is important to know how many of the members whose operations were not confirmed later had an operation for the condition screened, and how many required continued medical treatment. For confirmed cases, one should determine if presurgical screening affects the length of the hospital stay. Selected demographic characteristics and attitudes about presurgical screening of members using the program should also be surveyed.

The financial savings to both patients and third-party payers of unconfirmed procedures not being performed are probably substantial. If the average payment per hospital day by Blue Cross to hospitals in the lower 17 counties of New York State to date in 1974, \$141 (personal communication with the staff of Blue Cross Association of New York City), is multiplied by a weighted average of the length of stay for the nine most frequently unconfirmed diagnoses, 7.3 days,* an average cost per stay of \$1,029 is obtained. To this must be added the surgeon's fee, an estimated average of \$500 per procedure, and an esti-

*The data for the weighted-average length of stay based on the nine most frequently occurring diagnoses are from the Commission on Professional and Hospital Activities, *Length of Stay in PAS Hospitals, United States, Regional, 1972*. The length of stay for the East for persons 20 to 64 years of age with a single diagnosis was used.

mated average anesthesiologist fee, \$125. The total cost of a hospital stay, \$1,654, may be multiplied by the number of unconfirmed cases, 335, to yield an estimated savings of \$554,090 for the two programs in the given study period. The addition of savings from hospitalizations not required for 27 persons who had confirmed procedures done on an outpatient basis yields a total savings of \$581,873.

The expense of operating the presurgical programs and providing the consultations during the study period includes the cost per consultation and the average ancillary service charges, totaling \$28 per patient (this figure has risen to \$33 since the reporting period), and the direct administrative office costs for both programs of approximately \$37,300. Thus, the overall operating costs of the programs, \$75,268, compared to the total savings, \$581,873, represents a return of almost eight dollars for every dollar spent.

A presurgical consultation has benefits for the patient with a confirmed, as well as one with an unconfirmed, procedure. In a number of cases, discussion between the consultant and the patient's physician and ancillary studies, done as part of the consultation, alerted the patient's physician to a disorder as yet undetected.

To the patient and his family, the program offers reduced surgical risk and lessened anxiety. The program also experienced minimal difficulties with the member's physician who initially recommended that an operative procedure be done. Before the beginning of the program serious difficulties with obtaining co-operation of the member's physician in the execution of the presurgical screening were predicted. This forecast was inaccurate.

The experience of these two programs was instrumental in the establishment, as of July, 1973, of a voluntary presurgical screening program for New York State employees on a demonstration basis in the Albany-Syracuse area. Also in July, 1973, the Building Service Employees Welfare Fund Local 32-B, with approximately 150,000 persons covered, and the Trucking Employees of North Jersey Welfare Fund, with 50,000 persons covered, began a program of voluntary presurgical screening consultations in the same manner as described for the Storeworkers and District Council 37.

By and large, we believe we have documented the medical and economic advantages of establishing a screening program for elective surgical consultations for any insured population.

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MANDATORY AND VOLUNTARY SECOND OPINION PROGRAMS
IN THE GREATER NEW YORK AREA
WITH NATIONAL IMPLICATIONS

Presented by

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The Dorothy R. Eisenberg Lecture
Department of Surgery of the Harvard Medical School
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Second Opinion Consultation Programs owe their existence not primarily to health professionals, but to the foresight and perception of both union and management trustees of several Taft-Hartley Welfare Funds in the greater New York area. These welfare or security plans are the second largest purchasers of health care in the United States, with premium dollars in 1975 in excess of \$35 billion. Several of these trustees through the Cornell Labor School requested assistance in what they perceived was a significant medical care problem in our area, namely the possibility of surplus elective surgery.

Innumerable studies in the last 15 years, have shown the plausibility of surplus elective surgery, most notable in our area were the two Teamsters Studies Retrospective Case Review done by Trussel and Morehead. There has been a myriad of studies which have given circumstantial credence to the existence of the possibility of surplus elective surgery; the comparisons of national rates of surgery, regional comparisons of rates of surgery within the United States, density of surgeons related to the rates of surgery within certain states and counties within the United States, comparisons of the rates of surgery by type of third party coverage, etc.

These policy makers, namely the trustees, simultaneously have been faced with a sharp rise in health insurance premium demands as a result of the serious inflation in the medical care sector. Consistently, the inflation rate in the medical care component of the Consumer Price Index has moved at twice the rate of growth as other sectors of our economy in recent years. Even the Federal imposed price control mechanism in 1973-1974 has not effectively responded to this problem. In the greater New York area the surgical and anesthesia fee escalation has created a premium rise

in the last year alone of approximately 35 to 50 percent in the cost of Major Medical coverage for the Welfare Funds.

Add to this equation the market impact of the 1973-1974 recession on the reserves of private Welfare and Pension Funds, and you can begin to appreciate the stimulation to the Trustees to review all components of these Funds with a keen eye to effective cost containment.

The translation of an annual premium for acute hospital and physician care as a component of the wage package of an industry, can be demonstrated by the example of General Motors; their annual health premium in 1975 was \$735 million which rose without augmentation of benefits in 1976 to \$825 million or \$1,700 per employee on the payroll. Incidentally, the cost of the health benefit package to the U.A.W. employee exceeds the cost of steel for each 1976 model General Motor car -- \$575 per car.

The veritable explosive growth across the country of Elective Surgical Consultation Programs, in my opinion, has been caused in large part by the same recognition of these problems by trustees in other parts of the country that occurred in the greater New York area in the early seventies. Within recent months, third party health insurance providers (twenty-eight to date), both the Blues and commercial carriers, have established or will be establishing Second Opinion Elective Surgical Programs.

Government has also taken cognizance of the Second Opinion Program. In New York State, effective June 1st, a mandatory Second Opinion Consultation Program for Medicaid recipients has been passed by the State Legislature. CHAMPUS is planning to establish a demonstration Second Opinion Program in both San Diego and Tampa-St. Petersburg both areas where there is high concentration of military personnel and their dependents. Finally, New Jersey Commissioner of Insurance

required the New Jersey Blues to establish a Second Opinion Program as part of the rate increase for Blue Cross-Blue Shield in 1976-1977.

Thus, it is paramount to understand that the purchasers of care, be they trustees or government agencies are implementing Second Opinion Programs for Elective Surgery without quantitative measurement of surplus surgery. One trustee expressed it succinctly by indicating that consumerism, as we have seen it grow in other sectors of our society in recent years, has arrived in the surgical care field.

In the Spring of 1972, to carry out a Second Opinion Surgical Consultation Program for several Taft-Hartley Welfare Funds, Cornell University Medical College, Department of Public Health, established a grid of surgical consultants representing all of the surgical subspecialties in the greater New York area. These surgical consultants were all board-certified specialists affiliated with the major teaching institutions and several of the larger community suburban hospitals in the greater New York area.

Historically, the initial panel of board-certified specialists was created through my contacting the chiefs of the services of all the major medical schools and some of the teaching hospitals in New York and several of the suburban community hospitals. Our panel which is now in excess of 500 surgeons is a mixture of both academic based surgeons as well as community based surgeons. The emphasis from the very beginning was to structure a panel which mirrored the surgical community in our area. The predominance of our panel membership is, therefore, community based practicing surgeons. Within the last few months, we have augmented our panel both in New York and New Jersey with the active assistance of the respective chapters of the American College of Surgeons.

We have presented our research efforts in some detail at a special meeting of

the Board of Regents of the American College of Surgeons on Sunday, February 22nd. At that time, I requested the College to formally consider encouraging the creation of second opinion panels in response to either third party providers' requests or Taft-Hartley Welfare Fund requests. Prudential Insurance, for example, has so requested the College to assist in developing a program for its employees. Two senior staff men of the College, Jim Haug and John Pompelli, have surveyed the existing Second Opinion Programs around the country and have subsequently made certain recommendations to the Regents. My request of the College in February was to recognize and take cognizance of the existence and rapid growth of the Second Opinion Consultation Programs and assist in the structuring of panels to insure that criteria for panel membership is board certification and/or College membership.

If an insured member of one of the health and welfare plans was told by his physician that elective surgery was the next therapeutic step in his care, he would be able to request an appointment with a surgical consultant convenient to either his job or his residence.

Elective surgery has been defined by the membership of the funds as essentially all non-emergency surgery. Persons needing emergency surgery, such as results from trauma, would not be acceptable for screening.

Our research program commenced in February 1972 with the Storeworkers Welfare Fund composed of 20,000 insured Gimbels and Bloomingdales employees. This program was a mandatory Second Opinion Elective Surgical Consultation Program for all elective surgery. Mandatory, by definition in this program, is as follows: in order to obtain basic hospital and physician coverage for an elective surgical procedure, each insured member of Storeworkers was required to have a second opinion consultation prior to his or her admission for in-hospital elective surgery. Although the

program was intended to be compulsory, exceptions were made when the beneficiary lived too far away from the offices of the consultant, or when the waiting period for an appointment with the consultant was too long. The proportion of persons enrolled in the program but excused for the above reasons is 16%.

District Council 37 of the American Federation of State, County, and Municipal Workers, with 108,000 members (250,000 insured); Local 32B of the Building Service Workers, with 40,000 members (100,000 insured); and locals 560, 617, 641, and 660 of the Teamsters Union, with 15,000 members (40,000 insured); Typo-League Benefit Fund with 7,500 members (20,000 insured); New York City District Council of Carpenters Welfare Fund with 24,000 members (60,000 insured); Textile Processors Insurance Fund with 6,000 members (15,000 insured); inaugurated voluntary Second Opinion Surgical Consultation Programs. As distinct from the mandatory program, the voluntary program leaves to the insured the judgement whether he or she wishes to elect this new benefit of a second opinion. In both the mandatory and voluntary programs, the total cost of the physician consultation, as well as all ancillary service costs, are fully paid by the respective welfare funds.

The cost of each surgical consultation has been \$25 which will rise to \$40 as of July 1st. The composite cost per consultation for ancillary services has averaged approximately \$30. Thus, the overall consultation cost has averaged \$55 which will rise to \$70 as of July 1 of this year.

For all programs, a research team at Cornell keeps records of cases confirmed and not-confirmed for surgery. Table 1 shows the number of confirmed and not-confirmed consultations through March 31, 1976. In our program, there was a significant difference in the not-confirmed rate (NCR) between voluntary and mandatory groups ($\chi^2=120.96$, $p<.001$), due to the self-selection of the voluntary

programs. The resultant savings in hospitalization for the 1,099 not-confirmed cases represents approximately 2.4 million. The cost of operating the program in the same time frame approximates \$300,000. In addition, 3% of the confirmed surgery in the mandatory program was judged by the consultants not to require hospitalization. Prior to the second opinion consultation, hospitalization had been anticipated for this surgery.

Table 2 indicates the not-confirmed rate by the various specialties of the consultants. The category "other" includes the surgical specialties of plastic, cardiovascular, neurosurgery, and thoracic surgery. When comparing the NCR's by the various specialties of the consultants, one finds that the NCR for orthopedics and general surgery contributed to the variation between voluntary and mandatory groups. Chi-square tests were performed for these specialties, yielding a significantly higher NCR in orthopedics ($\chi^2=40.09$, $p<.001$ for voluntary group; $\chi^2=8.13$, $.001<p<.01$ for mandatory group) and a significantly lower NCR in general surgery ($\chi^2=49.72$, $p<.001$ for voluntary group; $\chi^2=15.74$, $p<.001$ for mandatory group) for both groups. Since the voluntary group had a greater proportion of orthopedic procedures accompanied by a high NCR, and the mandatory group had a larger proportion of general surgery procedures with a lower NCR, these rates were reflected in the difference of total NCR in the two groups. The voluntary group also had a significantly higher NCR ($\chi^2=21.33$, $p<.001$) in gynecology and a significantly lower NCR ($\chi^2=8.68$, $.001<p<.01$) in otolaryngology than all other surgical specialties.

Table 3 indicates the most frequently screened diagnostic categories by their not-confirmed rate. In the voluntary group there were significantly higher NCR's for hysterectomies ($\chi^2=11.39$, $p<.001$), and for surgery of the knee ($\chi^2=7.65$, $.001<p<.01$). In addition, compared to all other diagnoses, hernia and cholecystectomy

diagnoses yielded significantly lower NCR's.

Table 4 shows the not-confirmed rate according to the board-certified status and specialty of the initial diagnosing physician. Upon comparing the NCR for those whose initial physician was not boarded, we found no statistical difference for either the voluntary or mandatory group ($\chi^2=.04$, $.8(p<.9)$; and $\chi^2=1.83$, $.1(p<.2)$, respectively) to date. There was no difference in either group between those who went to a boarded surgeon and those who went to a non-boarded physician for their original diagnosis. There was also no statistical difference in NCR between those patients who went to boarded surgeons and those who went to other boarded physicians in the mandatory population. However, there was a significant difference in the voluntary group ($\chi^2=5.80$, $.01(p<.02)$; more specifically between boarded internists and all other boarded physicians with boarded internists having a lower NCR.

Among initial diagnosing physicians who were board-certified the NCR varies significantly with the specialty of the initial physician. In the voluntary program, the OB-GYN's and the orthopedic surgeons had a significantly higher rate of not-confirmed for surgery ($\chi^2=11.72$, $p<.001$; and $\chi^2=17.01$, $p<.001$ respectively). General surgeons had a significantly lower rate of not-confirmed compared to the NCR of all other board-certified surgeons in the voluntary group ($\chi^2=13.33$, $p<.001$). These findings are similar to those of the comparison of NCR's according to consultant specialty for the voluntary groups. They reflect the impact of self-selection, perhaps in requesting consultation for diagnoses that are more commonly questioned in the areas of orthopedic and gynecological surgery. The mandatory population, which represents a much more accurate cross-section of surgery for each specialty, has no statistical differences in NCR between the various board certifications of initial physicians.

At the present time we are referring 200 consultations a month which will

rapidly augment our numbers in the various subsequent categories outlined in this table. As the numbers increase, the interpretation of a statistical difference between boarded and non-boarded diagnostic physicians may change.

Table 5 shows the not-confirmed rate of New York City Employees in District Council 37 who have a choice of fee-for-service physician insurance coverage, Group Health, Inc. (GHI) and Blue Shield United Medical Service (UMS) or pre-paid capitation physician coverage under Health Insurance Plan of Greater New York (HIP). The data indicates a greater degree of agreement between HIP physicians and the consultants than between the consultants and physicians billing the fee-for-service carriers, where the rate of not-confirmed is greater.

Under our Social Security Study we are following all of the not-confirmed patients and an equal matched sample of the confirmed cases for a period of three years to ascertain what percentage of the deferred surgery subsequently underwent the necessity of surgical care. Through the documentation of utilization data, we will measure the alternative treatment cost incurred by this population. Likewise, in the matched sample of the confirmed population we are recording the utilization pattern subsequent to surgery to ascertain the treatment cost as a result of surgical care, for example; rehabilitation, medical treatment as a result of surgical infection, etc. The methodology is to contact with a fifteen minute phone interview questionnaire both of these respective populations. We will have claims confirmation from two of the Welfare Funds to assure the value of the data obtained from the phone interview.

We have contacted 392 voluntary not-confirmed out of a total of 499, or 79% of those seen by a consultant as early as July 1972 through March of 1975. 117 out of 143, or 82% of the mandatory not-confirmed have been contacted to date.

Table 6 shows the total number contacted for each group, by whether or not they had surgery after their consultation. 84% of the voluntary group not-confirmed, and 70% of the mandatory group did not have surgery after being screened by our consultants at least one year ago, and in some cases as long as four years ago.

Table 7 shows why the not-confirmed patients elected to undergo surgery. 40% of these people ignored the consultant's advice and had surgery without medical indications requiring the procedure, according to the board-certified surgical consultant. Almost 80% of these people were originally diagnosed by a board-certified physician. Half of the elected surgery of the voluntary group and 43% of the surgery performed for the mandatory group was required, according to the patient, because their symptoms persisted or worsened.

Table 8 shows that of the total not-confirmed by the consultants, only 8% of the voluntary group and 13% of the mandatory group consequently had surgery because of medical indications as reported by the patients.

As can be seen from Table 9 about three-quarters of all those who elected to undergo surgery had it performed within six months after their consultation. We will continue to follow up those people who did not have surgery, for at least one year since their consultation. The average initial follow up time is between two and three years, so that we do not anticipate any significant number of these people who have not had surgery to date, electing to have surgery after all.

Table 10 shows a distribution of the not-confirmed who did not have surgery according to whether they had medical treatment. 249 cases out of 413 or approximately 60% of the not-confirmed elective surgery population did not have medical treatment. One legitimately should question the reasons for the initial diagnosis of surgery in these cases.

153 out of 413 or approximately one-third of the non-confirmed population had

medical treatment with possible success. We will follow this medically treated group for an additional two year period. Thus, we will have followed all of the not-confirmed population for at least three years and in some cases as much as seven years subsequent to their second opinion consultation.

We have completed within the last few weeks the initial interview with a matched sample of confirmed population who have utilized the program from February 1, 1972 through March of 1975. Table 11 shows that in the voluntary program, 29% of those patients who were told by their initial physician and followed up by a confirmatory consultation with a board-certified specialist have not undergone surgery -- 9% of the sample of the mandatory confirmed population. These individuals are one year to four years since their second consultation in which the second opinion board-certified surgeon recommended or concurred with the initial physician that surgery was the next therapeutic step in their care. Our research hypothesis did not anticipate this degree of patient determined postponable elective surgery. Since this finding has come forth only in the last few weeks, we are analyzing this data further.

We are analyzing the diagnostic categories of those patients that have postponed surgery subsequent to dual physician confirmation of said surgery. The diagnostic categories for this patient postponed surgery subsequent to confirmatory physician recommendations is as follows.

Number Confirmed Who Did Not Have Surgery by Diagnoses With Large Frequency

	Vol. (Pop. 120)	Man. (Pop. 12)
	#	#
Foot surgery	6	0
Breast mass	6	2
Herniorrhaphy	7	1
Varicose vein ligation	8	0
Hand surgery	7	0
Cholecystectomy	9	1
Prostatectomy	7	0
Deviated septum	6	0
Heart surgery	5	0
Mass, cyst, or lesion	9	2
Hysterectomy	7	1
Ear surgery	9	0
TOTAL	86	7

We are altering our research design to further study and follow this patient determined deferred surgery population.

We feel that this data is the first quantitative estimate for what has been known for some time, namely the patient's election to indefinitely defer prescribed surgical care. Economic impact may be one of the ingredients for their course of action. Thus, one can speculate that when the financial barrier is lowered or eliminated there is a much greater unmet need of surgical care than we in medical care have hitherto appreciated -- apropos of introduction of national health coverage. One must keep in mind that the voluntary program sees approximately between 8 to 15 percent of the expected elective surgery. From an analysis of these diagnostic categories, the patients that opt for this benefit come from that portion of the spectrum of elective surgery which would be labeled serious or major surgical care. One of our research aspirations in the coming year is to analyze what motivations prompt certain patients in the voluntary program to utilize the Second Opinion Program.

One of the components of our research which is of equal importance to the following up of non-confirmed and confirmed population of the Second Opinion Consultation Program is the recognition of what we have labeled the "Sentinel Effect" of a Second Opinion Program. We have measured in the Storeworkers, approximately 9% drop in surgical claims in the time frame of 1972-1973 as compared with 1974 and 1975. Table 12 indicates the growth in most components of surgical care in recent years. The projection is that in 1976 we will have approximately 20 1/2 million surgical procedures in the United States.

As you can see from the example of H.E.W. Hospital Discharge Survey's most recent published data, there has been a significant increase in the rate of surgery well in excess of our population growth which is approximately 1% a year. The publicized

existence of a Second Opinion Program for Elective Surgery, whether it is voluntary or mandatory will have, we believe, a discernible effect on the recommendations for surgical care in elective surgery. With the New York State employees and their dependents, approximately 450,000, which has just commenced in the Program, we will be in a position to compare in a before-and-after study the rate of surgery by certain procedures for 1973-1974 as compared with 1978 and 1979. We will have a control group of same employees in other sections of the state.

The Second Opinion Program has profound educational impact upon the insured covered under these Taft-Hartley Welfare Funds. For the first time their union newspapers and magazines, and management newsletters clearly point out the value of board-certified surgical specialists. In the urban setting of New York, we still have approximately 30% of the surgery in the hands of non-boarded specialists. It does not take long for the insured to appreciate that if they go to a board-certified surgeon for a second opinion, they will use the same criterion in their selection of the surgeon to perform the surgery. In our opinion, this component of the Program has been a cause of controversy with certain County Medical Societies.

This presentation represents an interim report on our research to date and constitutes a very fascinating study in the delivery of surgical services. The increased utilization and cost of surgical care in the seventies, calls for the recognition on the part of the surgical community to support health services research in surgical care. Adequate accountability to the public for expenditures of funds from a tax base or from private health and welfare funds requires the active and wholehearted participation of the surgical community in the United States.

In our opinion, the impact of our findings more than justifies the wide adoption of the mechanism of second opinion elective surgery for appreciable improvement in the quality of care and effective cost utilization. The translation of this research

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project in medical care practice to the delivery system of care in such a brief time frame has been quite gratifying.

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TABLE 1. Participation in Elective Presurgical Screening Program, February 1972 Through January 1976

PARTICIPATION	CONFIRMED	NOT CONFIRMED
Total (N=3721)	70%	30% (N=1099)
Voluntary (N=2688)	65%	35% (N=932)
Mandatory (N=1033)	84%	16% (N=167)

χ^2 for Voluntary versus Mandatory rate of not confirmed, 120.96 ($P < .001$).

TABLE 2. Percent Not Confirmed for Elective Surgery According to Surgical Specialty

Specialty	VOLUNTARY		MANDATORY	
	Total Number	% Not Confirmed	Total Number	% Not Confirmed
General Surgery	749	24.6	463	11.0
Gynecology	474	43.7	258	19.4
Orthopedics	365	49.3	62	29.0
Otolaryngology	254	26.4	97	16.5
Urology	153	34.2	29	20.7
Ophthalmology	154	31.2	65	24.6
Other	219	38.4	37	10.8

TABLE 3. Percent Not Confirmed for Elective Surgery According to Most Frequently Screened Procedures

Procedure	VOLUNTARY		MANDATORY	
	Total #	% Not Confirmed	Total #	% Not Confirmed
Hysterectomy	271	44	89	20
D & C	84	40	119	16
Surgery of Knee	86	49	17	29
Surgery of Breast	150	30	91	12
Cholecystectomy	84	10	58	12
Herniorrhaphy	142	13	63	2
Prostatectomy	70	39	9	22
Cataract Removal	75	29	42	17
T & A	57	30	41	7
Varicose Veins	58	38	25	24

TABLE 4. Percent Not Confirmed for Elective Surgery According to Type of Board of Initial Diagnostic Physician

Board Status	VOLUNTARY		MANDATORY	
	Total Number	% Not Confirmed	Total Number	% Not Confirmed
Total Boarded	1185	33.5	605	14.7
D-S	307	25.1	184	11.4
D-OG	259	42.5	158	19.0
D-OS	162	47.5	58	17.2
D-OL	116	27.6	55	14.6
D-U	64	34.4	17	5.9
D-O	85	29.4	45	20.0
D-IM	126	23.8	52	15.4
Other ¹	99	35.4	49	10.2
Not Boarded	545	33	182	18.7

¹Includes D-PS, D-TS, D-NS, D-FP, D-CRS, D-D, and D-P.

TABLE 5. Percent Not Confirmed According to Type of Physician Health Insurance for District Council 37 of City of New York Employees

Insurance	Total Number	% Not Confirmed
Fee-for-Service	1274	37.9
GHI	1150	38.0
Blue Shield	124	37.1
Pre-Paid, HIP	769	30.3

TABLE 6. Number and Percent of Those Not Confirmed for Surgery During the Period 2/72 - 3/75 Who Elected to Have Surgery, Contacted Jan. 1976 - March 1976.

	VOLUNTARY		MANDATORY	
	<u>#</u>	<u>% Total</u>	<u>#</u>	<u>% Total</u>
Total Not Confirmed Contacted	392	100.0	117	100.0
No Surgery	331	84.4	82	70.1
Undergone Surgery	61	15.6	35	29.9

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TABLE 7. Reasons for Electing to Undergo Surgery for Those Not Confirmed .
During the Period 2/72 - 3/75.

	VOLUNTARY		MANDATORY	
	#	% Total	#	% Total
Total Undergone Surgery	61	100.0	35	100.0
Symptoms Persisted or Worsened	32	52.5	15	42.9
Ignored Consultant's Advice	25	41.0	14	40.0
Other ¹	4	6.5	6	17.1

¹Includes surgery not necessary but desired by patient, modified alternate procedure performed, and reason not specified.

TABLE 8. Persons Not Confirmed Who Had Surgery Because Their Symptoms Persisted or Worsened

	VOLUNTARY		MANDATORY	
	#	% Not Confirmed	#	% Not Confirmed
Total Not Confirmed	392		117	
Not Confirmed Who Had Surgery Because Their Symptoms Persisted or Worsened	32	8.2	15	12.8

TABLE 9. Number and Percent of Those Not Confirmed for Surgery During the Period 2/72 - 3/75 Who Had Surgery, According to When Surgery Was Performed.

	Total Surgery	Surgery Performed Six Months or Less After Consultation		Surgery Performed More Than Six Months After Consultation	
		#	% Total Surgery	#	% Total Surgery
Voluntary	61	43	70.5	18	29.5
Mandatory	35	27	77.1	8	22.9

medical treatment with possible success. We will follow this medically treated group for an additional two year period. Thus, we will have followed all of the not-confirmed population for at least three years and in some cases as much as seven years subsequent to their second opinion consultation.

We have completed within the last few weeks the initial interview with a matched sample of confirmed population who have utilized the program from February 1, 1972 through March of 1975. Table 11 shows that in the voluntary program, 29% of those patients who were told by their initial physician and followed up by a confirmatory consultation with a board-certified specialist have not undergone surgery -- 9% of the sample of the mandatory confirmed population. These individuals are one year to four years since their second consultation in which the second opinion board-certified surgeon recommended or concurred with the initial physician that surgery was the next therapeutic step in their care. Our research hypothesis did not anticipate this degree of patient determined postponable elective surgery. Since this finding has come forth only in the last few weeks, we are analyzing this data further.

We are analyzing the diagnostic categories of those patients that have postponed surgery subsequent to dual physician confirmation of said surgery. The diagnostic categories for this patient postponed surgery subsequent to confirmatory physician recommendations is as follows.

Number Confirmed Who Did Not Have Surgery by Diagnoses With Large Frequency

	Vol. (Pop. 120)	Man. (Pop. 12)
	#	#
Foot surgery	6	0
Breast mass	6	2
Herniorrhaphy	7	1
Varicose vein ligation	8	0
Hand surgery	7	0
Cholecystectomy	9	1
Prostatectomy	7	0
Deviated septum	6	0
Heart surgery	5	0
Mass, cyst, or lesion	9	2
Hysterectomy	7	1
Ear surgery	9	0
TOTAL	86	7

We are altering our research design to further study and follow this patient determined deferred surgery population.

We feel that this data is the first quantitative estimate for what has been known for some time, namely the patient's election to indefinitely defer prescribed surgical care. Economic impact may be one of the ingredients for their course of action. Thus, one can speculate that when the financial barrier is lowered or eliminated there is a much greater unmet need of surgical care than we in medical care have hitherto appreciated -- apropos of introduction of national health coverage. One must keep in mind that the voluntary program sees approximately between 8 to 15 percent of the expected elective surgery. From an analysis of these diagnostic categories, the patients that opt for this benefit come from that portion of the spectrum of elective surgery which would be labeled serious or major surgical care. One of our research aspirations in the coming year is to analyze what motivations prompt certain patients in the voluntary program to utilize the Second Opinion Program.

One of the components of our research which is of equal importance to the following up of non-confirmed and confirmed population of the Second Opinion Consultation Program is the recognition of what we have labeled the "Sentinel Effect" of a Second Opinion Program. We have measured in the Storeworkers, approximately 9% drop in surgical claims in the time frame of 1972-1973 as compared with 1974 and 1975. Table 12 indicates the growth in most components of surgical care in recent years. The projection is that in 1976 we will have approximately 20 1/2 million surgical procedures in the United States.

As you can see from the example of H.E.W. Hospital Discharge Survey's most recent published data, there has been a significant increase in the rate of surgery well in excess of our population growth which is approximately 1% a year. The publicized

existence of a Second Opinion Program for Elective Surgery, whether it is voluntary or mandatory will have, we believe, a discernible effect on the recommendations for surgical care in elective surgery. With the New York State employees and their dependents, approximately 450,000, which has just commenced in the Program, we will be in a position to compare in a before-and-after study the rate of surgery by certain procedures for 1973-1974 as compared with 1978 and 1979. We will have a control group of same employees in other sections of the state.

The Second Opinion Program has profound educational impact upon the insured covered under these Taft-Hartley Welfare Funds. For the first time their union newspapers and magazines, and management newsletters clearly point out the value of board-certified surgical specialists. In the urban setting of New York, we still have approximately 30% of the surgery in the hands of non-boarded specialists. It does not take long for the insured to appreciate that if they go to a board-certified surgeon for a second opinion, they will use the same criterion in their selection of the surgeon to perform the surgery. In our opinion, this component of the Program has been a cause of controversy with certain County Medical Societies.

This presentation represents an interim report on our research to date and constitutes a very fascinating study in the delivery of surgical services. The increased utilization and cost of surgical care in the seventies, calls for the recognition on the part of the surgical community to support health services research in surgical care. Adequate accountability to the public for expenditures of funds from a tax base or from private health and welfare funds requires the active and wholehearted participation of the surgical community in the United States.

In our opinion, the impact of our findings more than justifies the wide adoption of the mechanism of second opinion elective surgery for appreciable improvement in the quality of care and effective cost utilization. The translation of this research

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project in medical care practice to the delivery system of care in such a brief time frame has been quite gratifying.

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TABLE 1. Participation in Elective Presurgical Screening Program, February 1972 Through January 1976

PARTICIPATION	CONFIRMED	NOT CONFIRMED
Total (N=3721)	70%	30% (N=1099)
Voluntary (N=2688)	65%	35% (N=932)
Mandatory (N=1033)	84%	16% (N=167)

χ^2 for Voluntary versus Mandatory rate of not confirmed, 120.96 ($P < .001$).

TABLE 2. Percent Not Confirmed for Elective Surgery According to Surgical Specialty

Specialty	VOLUNTARY		MANDATORY	
	Total Number	% Not Confirmed	Total Number	% Not Confirmed
General Surgery	749	24.6	463	11.0
Gynecology	474	43.7	258	19.4
Orthopedics	365	49.3	62	29.0
Otolaryngology	254	26.4	97	16.5
Urology	153	34.2	29	20.7
Ophthalmology	154	31.2	65	24.6
Other	219	38.4	37	10.8

TABLE 3. Percent Not Confirmed for Elective Surgery According to Most Frequently Screened Procedures

Procedure	VOLUNTARY		MANDATORY	
	Total #	% Not Confirmed	Total #	% Not Confirmed
Hysterectomy	21	44	69	20
D & C	84	40	119	16
Surgery of Knee	86	49	17	29
Surgery of Breast	150	30	91	12
Cholecystectomy	94	10	58	12
Herniorrhaphy	142	13	63	2
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		#	% Total Surgery	#	% Total Surgery
Voluntary	61	43	70.5	18	29.5
Mandatory	35	27	77.1	8	22.9

TABLE 10. Number and Percent of Those Not Confirmed for Surgery During the Period 2/72 - 3/75, Who Did Not Have Surgery and Had Alternate Medical Treatment

	VOLUNTARY		MANDATORY	
	#	%	#	%
Total Not Confirmed Who Did Not Have Surgery	331	103.0	82	100.0
No Medical Treatment Needed	203	61.3	46	56.1
Medical Treatment Needed	117	35.4	36	43.9
No Information Available	11	3.3	0	0.0

TABLE 11. Number and Percent of Those Confirmed for Surgery During the Period 2/72 - 3/75, Who Did Not Have Surgery

	VOLUNTARY		MANDATORY	
	#	%	#	%
Total Confirmed Contacted	397	100.0	122	100.0
No Surgery	117	29.0	11	9.0
Undergone Surgery	280	71.0	111	91.0

TABLE 12. H.E.W. Hospital Discharge Survey: Number and Rate of Operations with Large Frequencies Performed for Inpatients Discharged from Short-Stay Hospitals - United States, 1968, 1971, 1973

<u>1968</u>	<u>1971</u>	<u>1973</u>	<u>% of Change</u> <u>1971-1973</u>
	# in Thousands		
14,624,000	15,774,000	18,426,000	17
T & A	967	884	-9
D & C (Diagnostic)	769	934	21
Hysterectomy	570	690	21
Cholecystectomy	373	411	10
Prostatectomy	207	249	20
Hemorrhoidectomy	213	218	2
Repair inguinal hernia	488	525	8
Extraction of lens	243	279	8
Reduction of fracture with fixation	263	284	8
Mastectomy	254	290	14

VOLUNTARY AND MANDATORY PRESURGICAL SCREENING PROGRAMS:

AN ANALYSIS OF THEIR IMPLICATIONS

Presented at

American Federation for Clinical Research
Clinical Epidemiology -- Health Care Research
Haddon Hall, Atlantic City
1:30 P.M., May 2, 1976

EUGENE G. MCCARTHY, MD, MPH, and ANN SUSAN KAMONS

Cornell University Medical College
Department of Public Health
New York, New York

Exhibit C

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Monitoring the quality of surgical care has traditionally been done in a hospital setting by retrospective chart review or by a panel of specialists reviewing post-operative cases. We describe a preoperative screening program that is prospective and relies on a surgeon's re-evaluation of the necessity of an operation as the next therapeutic step in the care of patients who have been informed by at least one physician that an operation is required.

Concern with both the quality of care that members were receiving and the questionable necessity for a proportion of the expenditures for hospitalization, led several Taft-Hartley union welfare funds to provide a mechanism for members about to undergo elective surgical procedures. In the Spring of 1972, to carry out a Second Opinion Surgical Consultation Program for these funds, Cornell University Medical College, Department of Public Health, established a grid of surgical consultants representing all of the surgical subspecialties in the greater New York area. These surgical consultants were all board-certified specialists affiliated with the major teaching institutions and several of the larger community suburban hospitals in the greater New York area. If an insured member of one of the health and welfare plans was told by his physician that elective surgery was the next therapeutic step in his care, he would be able to request an appointment with a surgical consultant convenient to either his job location or his residence. Elective surgery has been defined by the membership of the funds as essentially, all non-emergency surgery. Persons needing emergency surgery, such as results from trauma, would not be acceptable for screening.

The Second Opinion Program inaugurated by the Storeworker's Welfare Fund, composed of the 20,000 insured of Gimbel's and Bloomingdale's employees, was mandatory. Mandatory, by definition in the program, is as follows: in order to obtain basic hospital and physician coverage for an elective surgical procedure, each insured member of Storeworker's was required to have a second opinion consultation prior to his admission for in-hospital elective surgery. Although the program was intended to be compulsory, exceptions were made when the beneficiary lived too far away from the offices of the consultant, or when the waiting period for an appointment with the consultant was too long. The proportion of persons enrolled in the program but excused for the above reasons is 16%.

District Council 37 of the American Federation of State, County, and Municipal Workers, with 108,000 members (250,000 insured); Local 32B of the Building Service Workers, with 40,000 members (100,000 insured); and locals 560, 617, 641, and 660 of the Teamsters Union, with 15,000 (40,000 insured) members, inaugurated voluntary second opinion surgical consultation programs. As distinct from the mandatory program, the voluntary program leaves to the insured the judgement whether he wishes to elect this new benefit of a second opinion. In both the mandatory and the voluntary programs, the total cost of the physician consultation, as well as all ancillary service costs, are fully paid by the respective welfare fund.

For all programs, a research team at Cornell keeps records of cases confirmed and not-confirmed for surgery. Table 1 shows the number of confirmed and not-confirmed consultations through January 31, 1976. In our program, there was a significant difference in the not-confirmed rate (NCR) between voluntary

and mandatory groups ($\chi^2=120.96$, $p<.001$), due to the self-selection of the voluntary programs. The resultant savings in hospitalization for the 985 not-confirmed cases represents approximately 2.25 million. The cost of operating the program in the same time frame approximates \$300,000. In addition, 3% of the confirmed surgery in the mandatory program was judged by the consultants not to require hospitalization. Prior to the second opinion consultation, hospitalization had been anticipated for this surgery.

Table 2 indicates the not-confirmed rate by the various specialties of the consultants. The category "other" includes the surgical specialties of plastic, cardiovascular, neurosurgery, and thoracic surgery. When comparing the NCR's by the various specialties of the consultants, one finds that the NCR for orthopedics and general surgery contributed to the variation between voluntary and mandatory groups. Chi-square tests were performed for these specialties, yielding a significantly higher NCR in orthopedics ($\chi^2=40.09$, $p<.001$ for voluntary group; $\chi^2=8.13$, $.001<p<.01$ for mandatory group) and a significantly lower NCR in general surgery ($\chi^2=49.72$, $p<.001$ for voluntary group; $\chi^2=15.74$, $p<.001$ for mandatory group) for both groups. Since the voluntary group had a greater proportion of orthopedic procedures accompanied by a high NCR, and the mandatory group had a larger proportion of general surgery procedures with a lower NCR, these rates were reflected in the difference of total NCR in the two groups. The voluntary group also had a significantly higher NCR ($\chi^2=21.33$, $p<.001$) in gynecology and a significantly lower NCR ($\chi^2=2.68$, $.001<p<.01$) in otolaryngology than all other surgical specialties of consultants.

Table 3 indicates the most frequently screened diagnostic categories by

their not-confirmed rate. In the voluntary group there were significantly higher NCR's for hysterectomies ($\chi^2=11.39$, $p<.001$), and for surgery of the knee ($\chi^2=7.65$, $.001<p<.01$). In addition, compared to all other diagnoses, hernia and cholecystectomy diagnoses yielded significantly lower NCR's.

Table 4 shows the not-confirmed rate according to the board-certified status and specialty of the initial diagnosing physician. Upon comparing the NCR for those whose initial physician was boarded to that for those whose initial physician was not boarded, we found no statistical difference for either the voluntary or mandatory group ($\chi^2=.04$, $.8<p<.9$; and $\chi^2=1.83$, $.1<p<.2$, respectively). There was no difference in either group between those who went to a boarded surgeon and those who went to a non-boarded physician for their original diagnosis. There was also no statistical difference in NCR between those patients who went to boarded surgeons and those who went to other boarded physicians for the mandatory population. However, there was a significant difference in the voluntary group ($\chi^2=5.80$, $.01<p<.02$); more specifically between boarded internists and all other boarded physicians.

Among initial diagnosing physicians who were board-certified, the NCR varies significantly with the specialty of the initial physician. In the voluntary program, the OB-GYN's and the orthopedic surgeons had a significantly higher rate of not-confirmed for surgery ($\chi^2=11.72$, $p<.001$; and $\chi^2=17.01$, $p<.001$ respectively). General surgeons had a significantly lower rate of not-confirmed compared to the NCR of all other board-certified surgeons in the voluntary group ($\chi^2=13.33$, $p<.001$). These findings are similar to those of the comparison of NCR's according to consultant specialty for the voluntary groups. They reflect the impact of self-selection, perhaps, in requesting consultation for

diagnoses that are more commonly questioned in the areas of orthopedic and gynecological surgery. The mandatory population, which represents a much more accurate cross-section of surgery for each specialty, has no statistical differences in MCR between the various board certifications of initial physicians.

Table 5 shows the not-confirmed rate of New York City Employees in District Council 37 who have a choice of fee-for-service physician insurance coverage, Group Health, Inc, (GHI) and Blue Shield United Medical Service (UMS) or pre-paid capitation physician coverage under Health Insurance Plan of Greater New York (HIP). The data indicates a greater degree of agreement between HIP physicians and the consultants than between the consultants and physicians billing the fee-for-service carriers, where the rate of not-confirmed is significantly greater ($\chi^2=12.13$, $p<.001$).

Due to the publication of our research findings in the December 1974 issue of The New England Journal of Medicine, and at the 1975 Clinical Research National Meeting, there has been a rapid, even explosive, spread of the prospective Second Opinion Program. Approximately twenty-eight different Blue Cross-Blue Shield, commercial carriers, or independent union welfare funds have mounted or will activate a second opinion program this year. Because of the widespread acceptance of a Presurgical Screening Program, we have embarked on an evaluation of the impact of this program to ascertain what percent of the deferred elective surgical population subsequently required elective surgery.

We have contacted 392 voluntary not-confirmed out of a total of 499, or 79% of those seen by a consultant as early as July 1972 through March of 1975. 117 out of 143, or 82% of the mandatory not-confirmed have been contacted to date. Table 6 shows the total number contacted for each group, by whether or not they had surgery after their consultation. 84% of the voluntary group not

confirmed and 70% of the mandatory group did not have surgery after being screened by our consultant at least one year ago, and in some cases as long as four years ago.

Table 7 shows why the not-confirmed patients elected to undergo surgery. 40% of those people ignored the consultant's advice and had surgery without medical indications requiring the procedure, according to the board-certified surgical consultant. Almost four-fifth's of these people were originally diagnosed by a board-certified physician. Half of the elected surgery of the voluntary group and 43% of the surgery performed for the mandatory group was required according to the patient because their symptoms persisted or worsened.

Table 8 shows that of the total not-confirmed by the consultants, only 8% of the voluntary group and 13% of the mandatory group consequently had surgery because of medical indications as reported by the patients.

As can be seen from Table 9, about three-quarters of all those who elected to undergo surgery had it performed within six months after their consultation. We will continue to follow up those people who did not have surgery, after at least one year since their consultation. The average initial follow up time is between two and three years, so that we do not anticipate any significant number of these people who have not had surgery to date, electing to have surgery after all.

Table 10 shows a distribution of the not-confirmed who did not have surgery according to whether they had medical treatment. 249 cases out of 413 or approximately 60% of the not-confirmed elective surgery population did not have medical treatment. One legitimately must question the reasons for the

initial diagnosis of surgery in these cases.

153 out of 413 or approximately one-third of the non-confirmed population had medical treatment with possible success. We will follow this medically treated group for an additional two year period. Thus, we will have followed all of the not-confirmed population for at least three years and in some cases as much as seven years subsequent to their second opinion consultation.

A prospective second opinion elective surgical program utilizing board-certified surgeons after a careful follow up evaluation of the non-confirmed case for at least one year to four years, demonstrates that in the voluntary programs, one out of four screened patients, and in the mandatory programs, one out of seven and a half screened patients, appear to be permanently deferred.

The impact of our current findings more than justifies the wide adoption of the mechanism of second opinion elective surgery for appreciable improvement in the quality of care and effective cost utilization. The translation of this research project to medical care practice can significantly effect the delivery system of care in this country.

TABLE 1. Participation in Elective Presurgical Screening Program, February 1972 Through January 1976.

PARTICIPATION	CONFIRMED	NOT CONFIRMED
Total (N=3384)	71%	29% (N=985)
Voluntary (N=2373)	65%	35% (N=824)
Mandatory (N=1011)	84%	16% (N=161)

χ^2 for Voluntary versus Mandatory rate of not confirmed, 120.96 ($P < .001$).

TABLE 2. Percent Not Confirmed for Elective Surgery According to Surgical Specialty

Specialty	VOLUNTARY		MANDATORY	
	Total Number	% Not Confirmed	Total Number	% Not Confirmed
General Surgery	749	24.6	463	11.0
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TABLE 3. Percent Not Confirmed for Elective Surgery According to Most Frequently Screened Procedures

Procedure	VOLUNTARY		MANDATORY	
	Total Number	% Not Confirmed	Total Number	% Not Confirmed
Hysterectomy	271	43.9	89	20.2
Dilation & Curettage	84	40.5	119	16.0
Surgery of Knee	86	48.8	17	29.4
Surgery of Breast	150	30.0	91	12.1
Cholecystectomy	84	9.5	58	12.1
Herniorrhaphy - Inguinal	142	13.4	63	1.6
Tonsils & Adenoid-ectomy	57	29.8	41	7.3
Prostatectomy	70	38.6	9	22.2
Cataract Removal	75	29.3	42	16.7
Varicose Veins	58	37.9	25	24.0

Note: Foot surgery NCR was also examined, where of 110 cases, 53.6% were not confirmed for the voluntary group, and of 36 cases, 25.0% were not confirmed for the mandatory group. This diagnosis was not included with the above statistics because some of the patients had gone to podiatrists instead of M.D.'s for their initial diagnosis.

TABLE 4. Percent Not Confirmed for Elective Surgery According to Type of Board of Initial Diagnostic Physician

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Voluntary	61	43	70.5	18	29.5
Mandatory	35	27	77.1	8	22.9

TABLE 10. Number and Percent of Those Not Confirmed for Surgery During the Period 2/72 - 3/75, Who Did Not Have Surgery and Had Alternate Medical Treatment

	VOLUNTARY		MANDATORY	
	#	%	#	%
Total Not Confirmed Who Did Not Have Surgery	331	100.0	82	100.0
No Medical Treatment Needed	203	61.3	46	56.1
Medical Treatment Needed	117	35.4	36	43.9
No Information Available	11	3.3	0	0.0

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

THE MEDICAL SOCIETY OF THE STATE OF
NEW YORK, a New York not-for-profit
corporation, MORTON M. KOFF, M.D.,
MILTON ROSENBERG, M.D., and JANE DOE

Plaintiffs,

- against -

PHILIP L. TOIA, as Commissioner of the
Department of Social Services of the State
of New York and ROBERT P. WHALEN, M.D.,
as Commissioner of the Department of
Health of the State of New York,

Defendants,

AFFIDAVIT IN
OPPOSITION TO
A PRELIMINARY
INJUNCTION

STATE OF NEW YORK)
COUNTY OF ALBANY) ss:
CITY OF ALBANY)

J. RAYMOND DIEHL, JR., being duly sworn, deposes and
says:

1. I am the Acting Deputy Commissioner of the Division
of Medical Assistance of the New York State Department of Social
Services, 1450 Western Avenue, Albany, New York.

2. The purpose of this Affidavit in Support of
Defendant Toia is to specifically address the issue of relative
hardships on Plaintiffs and Defendants insofar as such hardships
relate to the need for granting a preliminary injunction re-
straining Defendants from implementing Chapter 76 of the Laws of
1976 and 10 NYCRR Part 85.

3. It is asserted that the named Plaintiffs, either
collectively or separately, will suffer no real or measurable
hardship from the implementation of Chapter 76 of the Laws of
1976 and 10 NYCRR Part 85, insofar as they relate to the implement-
ation of cost controls in surgical care, inpatient hospital stays
in excess of 20 days and inpatient pre-operative care in excess
of one day.

a) Plaintiff Medical Society of the State of New York
has failed to allege, or to present factual or other material,

indicating that it would suffer a hardship, substantial or otherwise, from the implementation of Chapter 76 and Part 85. Furthermore, it is apparent that, insofar as Chapter 76 was not designed to, and will not be implemented so as to, discourage individuals from entering or continuing the practice of medicine or to join Plaintiff Medical Society or any other organization of professionals, Plaintiff Medical Society will in no way be affected by the implementation of Chapter 76.

b) Plaintiff Morton M. Koff, M.D., has failed to demonstrate that he will suffer substantial hardship, individually or professionally, from Chapter 76 as implemented by 10 NYCRR Part 85. Plaintiff Koff has presented hypothetical cases as examples of surgical procedures which he has concluded would not be covered items of Medical Assistance. In no instance does he allege that an individual's medical condition is such that it can be alleviated only by surgery and that the surgery must be performed in the immediate future. The hypothetical cases cited by Plaintiff Koff may or may not be covered as items of medical assistance, depending on the individual circumstances of the case. The implementation of Chapter 76 has been and continues to be effectuated in such a way as to avoid asking Plaintiff Koff or any other physician to proceed with a surgical procedure at risk of financial loss to himself; indeed, it is being implemented so as to create an administrative process by which medical necessity can be determined prior to the performance of the procedure. Plaintiff Koff, on behalf of his hypothetical patients, has failed to demonstrate that he has availed himself of the administrative process by requesting a second opinion as to the necessity of the procedure and by requesting administrative review of a negative second opinion, if necessary. Plaintiff Koff has further failed to demonstrate that the requirement of obtaining a second opinion or of documenting the need for surgery

or continued inpatient hospital stays interferes with his right to practice medicine or to exercise professional discretion in such a way as to create a substantial hardship for him or his patients, in that some degree of documentation/^{to} establish medical necessity is necessary in every situation in which a party other than the one being treated provides payment for services rendered, including Medicaid, Medicare and third party insurers, and could and probably should be requested by patients who pay for their own care. The Department of Social Services and the Department of Health, in consultation with a number of practitioners and professional groups, have implemented Chapter 76 in a manner consistent with its purpose of requiring the second opinion, not in all surgical situations, but only in those situations which can be identified as being medically necessary in some cases and unnecessary in other cases, depending on individual circumstances.

c) Plaintiff Milton Rosenberg, M.D. has failed to demonstrate that he will suffer substantial hardship for all those reasons cited above with respect to Plaintiff Koff. In addition to hypothetical cases cited, Plaintiff Rosenberg has in addition cited the case of Jane Doe as an individual who has been denied medical treatment because of the implementation of Chapter 76. Moreover, insofar as Plaintiff Rosenberg had not demonstrated that he performed surgery and was denied payment, he has failed to demonstrate that he has or will suffer any financial loss. Insofar as Plaintiff Rosenberg has failed to demonstrate that all available administrative processes have been exhausted and that medical assistance payments for the surgery would be denied if the procedure were performed, Plaintiff Rosenberg has failed to demonstrate that his right to practice medicine or to exercise professional discretion has been or will be interfered with in such a way as to constitute any hardship.

d) Plaintiff Jane Doe has failed to demonstrate that she has suffered any hardship as a result of the implementation of Chapter 76, insofar as she has not alleged that she requested a second opinion as to the necessity of performing the surgical procedure, that she has received a negative second opinion and that she has exhausted all administrative appeals. Furthermore, she has failed to allege that the medical condition from which she suffers can, in the professional opinion of her physician, only be treated by a surgical procedure, and cannot be treated with the same or less risk by other inpatient or outpatient procedures. Persons with similar physical conditions have undergone diagnostic surgical procedures which have been found to be covered items of medical assistance. Finally, it is noted that implementation of Chapter 76, as outlined in 10 NYCRR Part 85, may prove of benefit rather than harm to Plaintiff Jane Doe, in that it may result in the avoidance of unnecessary surgery with attendant risks associated with such surgery.

e) Raymond Ortega is not recognized by Defendants as a proper party to this action in that supplemental summons was not served in a timely manner. However, assuming that Raymond Ortega were properly joined as a party plaintiff, he has failed to demonstrate that he has or will suffer any hardship for all those reasons cited above with respect to Plaintiff Jane Doe. In addition, it is noted that the medical condition of Raymond Ortega results from an incident that occurred over ten years ago ~~and during the intervening ten years was not treated by surgery.~~ The necessity for surgery at this time must be evaluated on the basis of such factors as the affect the condition will have on Raymond Ortega's ability to find employment, ability to engage in essential social functions, and necessity to avoid substantial continuing disability, including psychological

disability. Each of these factors are required to be considered in determining medical necessity under Chapter 76 as implemented by 10 NYCRR Part 85, and until such factors have been considered and a negative second opinion has been obtained, no harm to Raymond Ortega has been demonstrated.

4. The granting of a preliminary injunction in this proceeding will create grave fiscal and socio-medical consequences to THE PEOPLE OF THE STATE OF NEW YORK, including the individual plaintiffs, in that

a) An injunction against implementation of 10 NYCRR Part 85 ~~will~~^{would} cost New York State \$65,000,000 per year based upon projections developed jointly by officials from the State Departments of Health, Social Services, Audit and Control and the Governor's Office who are familiar with financial aspects of the Medicaid program. This figure constitutes more than \$1,000,000 per week of the limited resources available to the Medicaid program. It is noted in this regard that in his testimony of August 26, 1976 Mr. Douglas Evans of this Department incorrectly stated the fiscal impact. He had erroneously based his figures on the total Medicaid cost containment package, Chapter 76 of the Laws of 1976. In fact however that package contains cost controls not here in issue. Attachment A to this affidavit displays the total projected savings of the Legislative enactment. However, only the savings projected in items b,c,d and e are relevant to this action.

b) As this Court is no doubt aware, New York City and the entire State faces a fiscal emergency of staggering proportions. Investors in municipal and State bonds are keeping a close watch on those proceedings to see if New York State can, as promised, achieve cost containment and retain fiscal solidity. The granting of a preliminary injunction in this matter may, combined with other factors, make New York State unable to attract investors during a critical period.

c) Possibly more compelling than the figures presented, however, is the cost, in terms of potential individual harm, that could result from the issuance of a preliminary injunction and the State's consequent inability to implement Chapter 76. 10 NYCRR Part 85 is designed to allow indigents who need surgery to obtain such surgery with minimal additional administrative requirements over those that have been in operation since the inception of the Medicaid program. Medical necessity has always been the Medicaid standard in this State. Furthermore, Doctors Wharton and McCarthy have pointed out the studies documenting the abuses suffered by persons who were subjected to needless surgery with the concomitant discomfort and debilitation associated with any surgical care. Clearly, 10 NYCRR 85.1 and 2 provide for immediate treatment for persons exhibiting obvious medical necessity. Only where there is clearly a question of medical necessity depending on the condition of the individual is a second opinion required under 10 NYCRR 85.3. The State of New York will not categorically refuse to provide Medicaid for any type, group or description of surgery. The State will, however, require a second confirming opinion to protect its indigent citizens from needless suffering in certain established areas. Plaintiffs suggest that hospital utilization review committees can accomplish what Part 85 sets out to do. Plaintiffs are totally misguided in their perception of the function of these committees. Utilization review is a post-admission, and in most cases, post-surgical, procedure. Part 85 provides for pre-admission review. Utilization review has pointed out instances of Medicaid abuse but has been unable to prevent them. Part 85 is designed to fill that void.

d) From the above and the affidavits heretofore submitted it is manifest that the granting of an injunction herein will increase costs to the taxpayers of New York State, including the individual plaintiff doctors. In addition, limited resources

designed to benefit indigents requiring medically necessary surgery will be misutilized for persons who, though indigent, do not require surgical intervention.

5. In summary, it is asserted that while Plaintiffs, individually or collectively, will suffer no substantial hardship from the continued implementation of Chapter 76 of the Laws of 1976, as outlined in 10 NYCRR Part 85, the State will suffer substantial hardship and possibly irreparable damage as a result of the issuance of a preliminary injunction and the consequent inability of the State to continue implementation of Chapter 76. It is therefore requested that the relief sought by Plaintiffs be denied.

S/ 8/30

J. RAYMOND DIEHL, JR.

Sworn to before me this
30 day of August, 1976

S/

NOTARY PUBLIC

Anticipated Savings through the Implementation
of Hospital and Outpatient Clinic Portion of
Cost Containment Legislation (Chapter 76 of the
Laws of 1976)

Hospital Care:

* Dollars in Millions:

A. The result of holding Inpatient Hospital rates to a 1975 reimbursement level (pure rate) were anticipated to result in gross savings for a fiscal year of:	145.0
B. Elimination of non-medically necessary surgery was anticipated to result in annual savings of:	5.0
C. Requiring a 2nd opinion on deferrable optional surgery was anticipated to yield savings annually of:	15.0
D. Limiting reimbursement for pre-surgical stays for authorized surgeries to one day was anticipated to yield gross savings annually of:	5.0
E. Limiting reimbursement for hospital care to 20 days per spell of illness, unless medically certified that continued care is essential, resulting in anticipated gross fiscal (based on \$120 million Medicaid payments per year in over 20 day stays) of:	40.0
F. Decertification of unnecessary beds; the fiscal implication of eliminating oversupply of hospital beds, except where geographically viable alternatives did not exist and was anticipated to generate gross annual savings of:	100.0
G. A reduction of 10% on the Outpatient clinic rates was anticipated to generate a gross annual savings of:	60.0
Total estimated gross savings from In-Patient Hospitalization and Outpatient Clinic Services	370.0 per yr.

*These amounts represent anticipated savings for the first full annual period projected, as of March, 1976

.....X

File

File 76 CIV. 1443

PHILIP TOIA, as Commissioner of the Department of Social Services of the State of New York and Robert P. Whalen, M.D., as Commissioner of the Department of Health of the State of New York,

State of New York)
County of Albany) SS
City of Albany)

1. That I am the Second Deputy Commissioner of the New York State Department of Health. My responsibilities include developing policy and implementing activities of the Medical Assistance for the needy program (Medicaid).

Medical Center.
3. That Deponent is familiar with the facts, circumstances and issues in this litigation as they relate to the functions of the New York State Department of Health and has read the affidavits submitted in support of and in opposition to the requested preliminary injunction as well as the depositions taken on the 26th day of August 1976 of Drs. Koff, Seinfeld and Alchek and of Mr. Evans.

4. That this affidavit is made in support of defendant Commissioner Robert P. Whalen's opposition to plaintiff's motion for a preliminary injunction.

5. That there is no indication that the plaintiff physicians made any effort to determine that there was coverage in the situations they relate. It appears affirmatively that considerations other than medical necessity dictated their actions. For example, "we're being bombed with the thought of paperwork" (Seinfeld deposition, page 13). Although plaintiff physicians testified as to having a knowledge and understanding of the law upon which they made a determination that they could not care for the patients (Dr. Seinfeld deposition page 16, lines 11 and 14), they indicated they had no knowledge of the implementing regulations (Dr. Seinfeld deposition, page 16). Chapter 76 has specific reference to the issuance of regulations by the Commissioner of Health. The implementing regulations were provided to all hospitals and social services districts in the State of New York as well as The State Medical Society, plaintiffs in this proceeding.

6. That in prejudging coverability with incomplete knowledge and in making no attempt to secure the admission of patients who upon the facts stated may very well be within Chapter 76, there is no demonstration of hardship or prejudice to the plaintiffs.

7. That reimbursement has been made under Chapter 76 for procedures alleged by plaintiffs to be unavailable under such statute. See attachment No. 1.

8. That the condition of plaintiff Jane Doe, if she is otherwise eligible for Medicaid benefits, would constitute a covered benefit for immediate diagnosis (85.1). The further necessity for the urgent or emergency use of the surgical diagnostic procedure, dilation and curettage, as set forth in Dr. Wharton's affidavit sworn to August 20, 1976, is confirmed in the deposition of Dr. Seinfeld (page 16, lines 5-8).

9. Doctor Edgar Alchek stated that he personally saw plaintiff Ortega in the plastic surgery clinic "in preparation of this case" (Alchek deposition page 7, lines 17-19), that Mr. Ortega is severely distressed by his appearance and emotionally disturbed, and that the contracture, if not corrected, would cause damage to Mr. Ortega's eye. He further stated that admission was not requested by him, that the resident told him the surgery would not be coverable, and he does not know of any appeal. The regulations provide for an appeal by the surgeon in case of a determination of non-coverability by the Commissioner's designee. There is thus no indication that established procedures have been followed and that the surgery proposed for Mr. Ortega has been denied or if denied that an appeal has been taken.

10. That plaintiff physicians assert that they do not know what the terms "essential function", "threaten life or essential function" or "severe pain" mean in the context of the law (Seinfeld deposition page 12, lines 19 through 25, page 13, lines 1 through 3). It is interesting to note that these very same physicians made a determination that a deferral of surgery for six months would not "threaten her life or essential function or cause her severe pain" (Seinfeld deposition, page 7, lines 20-23). The plaintiffs themselves argue that "essential function" has a commonly understood meaning in English.* Webster defines essential as basic, indispensable, necessary, inherent. Some functions are essential to every person, breathing for instance. Other functions are essential ^{To} the specific case, such as employability.

* Plaintiffs Reply Memorandum Pg. 7

The applicable use of the word severe as used in Chapter 76 is defined by Webster's New International Dictionary, Unabridged, as meaning "of a great degree or an undesirable or harmful extent." Pain is felt only ^{by} the patient, but is shown, expressed or described by the patient and evaluated by the physician in establishing a diagnosis and plan of treatment. Severe pain would therefore include a consideration of the degree or harmful extent of such pain. The physician would, to the best of his ability, determine the degree of pain and whether its extent is harmful to the patient. The practice of medicine itself is defined as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition" (emphasis added).

Certainly "life threatening" is a term understood generally by the medical profession.

11. That it appears from the report of the Subcommittee on Oversight and Investigation of the Committee on Interstate and Foreign Commerce, submitted to the court, that Medicaid patients have nearly 2-1/2 times the frequency of surgery as compared to the total United States population generally (page 42, 18.7/100 v. 7.9/100)

12. That by regulation (§85.3 (d)) the Commissioner of Health has mandated a second opinion for the seven types of procedures set forth therein, when not an emergency or urgent. The studies of Dr. McCarthy (previously submitted to the court with the affidavit of Dr. McCarthy) have shown that five of the types of procedures set forth (tonsillectomy/ adenoidectomy, herniorrhaphy, hysterectomy, cholecystectomy and knee surgery) very often fail to meet with second opinion concurrence. These five procedures, together with hemorrhoidectomy and spinal fusion or laminectomy constitute 15% of the surgical procedures performed.

13. That to enjoin the implementation of Chapter 76, §§ 3, 4 would impose a hardship upon the State and upon Medicaid beneficiaries by permitting the continuation of the unnecessary surgery at which Chapter 76 is directed with the consequent unnecessary risk to the patient. It would enable excessive hospital stays to continue with debilitating effect upon the patient (see Dr. Wharton's affidavit, page 10, paragraph 25), and may allow the Medicaid program to be so burdened with unnecessary procedures and stays, as to jeopardize the resources available for delivery of necessary services to those eligible.

Frank T. Cucco M.D.

Sworn to before me

this 30th day of August, 1976

Joseph P. Donovan
Notary Public, State of New York
Qualified in Westchester County
my Commission expires 3/30/78

TYPES OF CASES DETERMINED COVERABLE RECENTLY
UNDER CHAPTER 76 AND PART 85

Hospital B - Case 55033-2. Vaginal paramenopausal bleeding. Admitted August 10, 1976. Dilatation, curettage and biopsy performed.

Case 058711-0. Metrorrhagia. Admitted August 11, 1976 for diagnostic workup.

Case 147599-9. Stress incontinence, cystocoele. Admitted August 8, 1976 for vaginal hysterectomy and repair.

Case 541452-1. Endocervical polyps with bleeding. Admitted August 10, 1976 for dilatation, curettage and polypectomy.

Case 082091-0. Class III Pap Smear, uterine dehiscence. Admitted August 9, 1976 for vaginal hysterectomy.

Case 180756. Asymmetry of breasts. Admitted August 11, 1976 for reduction mammoplasty.

Hospital C - Case 002244. Suspect Pap Smear. Admitted August, 1976 for bilateral salpingo-oophorectomy and hysterectomy.

Hospital R - Case 522089. Cystocoele, rectocoele. Admitted for dilatation and curettage, vaginal hysterectomy and repair.

(B is Bellevue, C is Cabrini, and R is Roosevelt)

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BY hand by

Melba T. Caliano

AT 4¹⁰ pm ON 3-30, 1977